UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION FOR LEAVE TO AMEND MASTER COMPLAINTS

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Co-Lead Plaintiffs' Counsel, on behalf of the Plaintiffs' Executive Committee, pursuant to the Special Master Order No. 18 dated May 4, 2021, (ECF 1217), respectfully file this consolidated Reply Memorandum of Law in further support of their Motion for Leave to Amend the Master Complaints[1] (ECF 1148), and in response to the opposition briefs filed by the Manufacturer Defendants (ECF 1277) (hereafter referred to as "Manuf. Br."), Wholesaler Defendants (ECF 120) (hereafter referred to as "Wholesaler Br."), and Retail Pharmacy Defendants (ECF 1281) (hereafter referred to as "Retail Pharmacy Br.")

I. INTRODUCTION

On December 18, 2020, the Court entered the first of six orders ruling on Defendants' motions to dismiss the three Valsartan Master Complaints ("MTD"). *See* ECF 675-676. With few exceptions the Court denied the motions or granted them in part without prejudice with leave to file a motion to amend. *See, e.g.*, ECF 728-729 (Order and Opinion No. 2); ECF 775-776 (Order and Opinion No. 3); ECF 818-819 (Order and Opinion No. 4); ECF 838-839 (Order and Opinion No. 5); ECF 1019-1020 (Order and Opinion No. 6).[2]

Plaintiffs' proposed amendments were made in direct response to the Court's motion to dismiss rulings. Claims dismissed with prejudice (*e.g.*, the Magnuson-Moss claim) have been removed from the proposed amendment complaints. Claims or matters that the Court said could be re-pleaded have been amended with added factual or legal detail to address whatever issue the Court identified in its dismissal rulings. These include, for instance, amplifying the factual

[1] The operative versions of the master complaints are referred to herein as the Personal Injury Master Complaint ("PIMC"), the Economic Loss Master Complaint ("ELMC"), and the Medical Monitoring Master Complaint ("MMMC"). The proposed amended versions of these complaints each add a "P" to the foregoing, i.e., the PPIMC, the PELMC, and the PMMMC.

[2] For ease of reference and brevity, the Court's six Orders and Opinions will be referred to by number as "MTD Order No. X" throughout this brief.

allegations concerning each named plaintiff's purchases of valsartan (per MTD Order No. 2) or the warranty claims against certain downstream defendants (per MTD Order No. 3). The fact that the Court expressly permitted Plaintiffs the opportunity to seek leave to amend negates any potential suggestion of undue prejudice to the Defendants or bad faith on the part of the Plaintiffs. Similarly, there is no undue delay because Plaintiffs' motion is filed within the time provided by Special Master Order No. 4.

This only leaves the Defendants with the ability to argue that the proposed amendments are futile. However, as more fully discussed below, each of the Plaintiffs' proposed amendments address a specific issue on which the Court invited amendment in its motion to dismiss rulings. Had the Court believed no set of facts could have established a given claim, it could have dismissed the claim with prejudice. That the Court did not dismiss these claims with prejudice underscores the appropriateness of Plaintiffs' proposed amendments.

In their combined 150 pages of briefing, the Defendants attack Plaintiffs' proposed amendments and request that the Court make factual determinations as though this were a Motion for Summary Judgment, and not a Motion for Leave to Amend filed pursuant to the Court's disposition of broad Rule 12(b)(6) briefing. Defendants' arguments are directly at odds with the Third Circuit, which has instructed District Courts that, "leave to amend 'shall be freely given when justice so requires;' this mandate is to be heeded." *Heyl & Patterson Intern., Inc. v. F.D. Rich Housing of Virgin Islands, Inc.*, 663 F.2d 419, 425 (3d Cir. 1981).

In addition to their request that the Court deny Plaintiffs' Motion for Leave to Amend based on misleading factual grounds not actually applicable in this procedural posture, Defendants appear to simultaneously argue the opposite approach in asking the Court to deny the Motion for Leave based on a specific syntactical wording argument as to a handful of the paragraphs (out of

over 500 or more paragraphs) in the Plaintiffs' complaints. This is also contrary to the spirit of the complaint amendment process, which does not penalize a party for "failing to invoke magic legal words" in a complaint. *Rosedale & Rosehill Cemetery Ass'n v. Twp. of Reading*, -- F. Supp. 3d --, 2020 WL 7768457, at *6 (D.N.J. Dec. 30, 2020). To the extent Defendants insist on dickering with Plaintiffs' word choice, such matters are immaterial and easily corrected with a word processor.[3] *See* Exs. A-C hereto (revised amended master complaints).

Because Plaintiffs directly responded to the Court's rulings in their proposed amendments, Plaintiffs' proposed amendments are not futile, do not threaten undue delay, are not motivated by bad faith, and do not unfairly prejudice the Defendants. As such, Plaintiffs ask the Court to overrule the Defendants' objections and grant their Motion for Leave to Amend.

II. <u>ARGUMENT</u>

A. Standard of Review

Defendants do not dispute the liberal standard for amendment under Federal Rule of Civil Procedure 15. Defendants merely argue that Plaintiffs did not cure all the pleadings deficiencies identified in the Court's orders on the motions to dismiss; that failure to cure will result in undue prejudice to Defendants; and that amendment remains futile as to certain claims.

Granting leave to amend should ordinarily only be denied when the defendant can show that the amendment would be futile, was the result of undue delay, motivated by bad faith, or that the defendant would be unfairly prejudiced by the court's granting leave. *Cureton v. NCAA*, 252 F.3d 267, 272-73 (3d Cir. 2001). Notably, "delay alone is an insufficient ground to deny leave to

[3] In order to cure many of the ministerial and administrative deficiencies Defendants make in their briefing, Plaintiffs have appended newly revised and amended master complaints to alleviate Defendants' concerns. *See* Exs. A-C (revised amended master complaints). These amendments are further discussed *infra* at §II.E.

amend." *Id.* (citing *Cornell & Co., Inc. v. Occupational Safety & Health Rev. Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978)). "The Third Circuit has contemplated that the standard for denial of amendment is high, stating '[g]enerally, Rule 15 motions should be granted.'" *Microbilt Corp. v. Certain Underwriters at Lloyds, London*, No. 20-12734, 2021 WL 1214774, at *2 (D.N.J. Mar. 31, 2021) (quoting *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016)).

Futility is analyzed under the standard for determining legal sufficiency under Rule 12(b)(6). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Amendment should only be denied when, construing all allegations in the plaintiff's favor, the amendment would fail to state a claim upon which relief could be granted. *Id.* Because of the liberal standard applied to amendments, the courts place a "heavy burden" on an opponent who challenges the amendment on the grounds of futility. *Pharm. Sales & Consulting Corp. v. J.W.S. Delavau Co.*, 106 F. Supp. 2d 761, 764 (D.N.J. 2000).

B. Plaintiffs are Permitted to Add Factual Allegations

Contrary to the Defendants' exhortations, Plaintiffs do not seek to add some "[n]ew and [u]nathorized [t]heory of [l]iability" into the proceedings. Manuf. Br. at 32.

1. Official Compendium Allegations

The allegations related to the official compendium which Defendants now proclaim are somehow "new" and "unauthorized" are actually allegations that have been referenced or touched upon in the Plaintiffs' Complaints since June of 2019. *See* ECF 121. For example, Plaintiffs made reference to the compendium (ELMC ¶¶ 156, 157), alleged that Defendants made false statements (ECF 121 at ¶ 173), and explained that the Defendants' drugs did not comport with the Orange Book Standard (ECF 121 at ¶¶ 352-366). These allegations can hardly come as a surprise as the

Court explicitly referred to the Defendants' failure to satisfy those representations in denying the Defendants' motion to dismiss the express warranty claims.

> The Court finds the FDA has already made an initial determination as to the general bioequivalence when it recalled the VCDs at issue. That is, the recall serves to point out that the VCDs at issue contained contaminants not listed in the Orange Book and makes the Court's starting point as to the VCDs' lack of general chemical bioequivalence plain and simple.

MTD Order No. 1 at 16.

More pointedly, Plaintiffs did not add any additional causes of action to their proposed amendment. Rather, Plaintiffs simply added some additional facts and clarifications. In similar situations where the plaintiff seeking leave to amend under Rule 15 is merely adding factual allegations, this Court has freely given leave to amend. *See Campbell v. Sedgwick Detert, Moran & Arnold*, No. CIV. 11-642-ES-SCM, 2013 WL 1314429, at *6 (D.N.J. Mar. 28, 2013). Indeed, it is typical and countenanced by the Federal Rules that a plaintiff may amend a complaint based on evolving discovery, all the way through the time of trial and even through appeal. *Gov't Employees' Retirement Sys. of V.I. v. Gov't of V.I.*, 995 F.3d 66, 82 & n.11 (3d Cir. 2021). Moreover, because these allegations have largely been in the complaint since 2019, Defendants cannot in any way credibly argue they have been unfairly prejudiced by the inclusion of this language. *D'Onofrio v. Borough of Seaside Park*, No. CIV.A. 09-6220 AET, 2012 WL 5989437, at *5 (D.N.J. Nov. 29, 2012).

Defendants also mischaracterize Plaintiffs' claims by alleging that Plaintiffs somehow seek to "delist" the Manufacturer Defendants' drugs from the Orange Book. Whatever that may mean, it is not an argument to preclude amendment. Plaintiffs do not seek such relief anywhere in any complaint. Instead, Plaintiffs alleged that the Manufacturer Defendants failed to manufacture drugs that were not the same product as their branded counterparts and instead Defendants made

drugs containing highly carcinogenic substances. *See, e.g.*, PPIMC ¶¶ 200, 203–05.

Plaintiffs do, however, continue to maintain legally sound causes of action against the Manufacturer Defendants for failing to manufacture drugs which conform to the standards in the Orange Book, USP, or other official compendia, and which are adulterated and misbranded. *See* PPIMC ¶¶ 590-93, 606, 615, 629-34, 647-55, 667, 671-72, 765; *see also* MTD Order No. 1 at 16. However, as discussed *supra*, these are not new allegations – they have been present in the complaints the entire course of the litigation.

Because Plaintiffs do not seek to privately enforce any part of the FDCA, as already stated in their proposed master pleadings, *see, e.g.*, PPIMC ¶ 635, Defendants' repackaged preemption argument necessarily fails. The Court already ruled on this very issue in its first Motion to Dismiss Opinion. *See* MTD Order No. 1, at 12.

2. Allegations Regarding the Value of the Product

Defendants fret over a couple of purportedly ambiguous lines in the 500+ paragraph PELMC, arguing that Plaintiffs are alleging a "less valuable" product theory. Plaintiffs do no such thing. Plaintiffs allege a "no value" product theory in the PELMC, not a "less valuable" product theory. While Plaintiffs do not believe such an amendment to be necessary, Plaintiffs have revised their proposed amended complaint to specifically exclude the allegations which under a strained reading might imply they are pursuing a "less valuable" product theory. *See* Exs. B-1, B-2.

C. Plaintiffs Have Standing and Their Injuries Are Traceable to Defendants

The Court's MTD Order No. 2 identified two areas in the ELMC and MMMC for Plaintiffs to address via amendment: traceability and out-of-state absent class members. Plaintiffs' amendments adequately address both of these issues.

1. Class Plaintiffs' Injuries Are Traceable to Defendants

For Plaintiffs to show traceability, an "indirect causal relationship will suffice." *Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000). This standard is less than the proximate causation needed to succeed on the merits of a tort claim. *See Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64, 72 (3d Cir. 1990). Article III does not require Plaintiffs to plead precisely who among plausible tortfeasor Defendants caused each and every one of their injuries, and to suggest otherwise would "raise the standing hurdle higher than the necessary showing for success on the merits." *Friends of the Earth, Inc. v. Laidlaw Envir. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000). This is especially true in complex pharmaceutical cases involving multiple actors in the drug supply chain such as manufacturers, distributors, wholesalers, and pharmacies. Notwithstanding the above, Plaintiffs *have* supplied detailed allegations regarding i) the business practices of the Defendants which allows for product tracing, and ii) each Defendant that was involved at every level of the supply chain that resulted in a specific Plaintiff purchasing a VCD.

Taking the allegations of the PELMC and PMMMC as true, Plaintiffs' injuries more than exceed the baseline standard necessary to show sufficiently plead traceability. Amended allegations in the PELMC and PMMMC describe, in painstaking detail, the granular level of data each Defendant maintains (and must maintain, as a matter of law) that permit product identification and tracing. *See* PELMC ¶¶ 170-196; PMMMC ¶¶ 144-163. For instance, each drug sold in the United States is encoded with "a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing." *See* PELMC ¶¶ 197-200; PMMMC ¶¶ 164-166. "The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer;

and from the retailer to the consumer) and therefore every transaction is accompanied by and labeled with the NDC." PELMC ¶¶ 177-179; PMMMC ¶¶ 144-146. "This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase." PELMC ¶¶ 177-179. Each Manufacturer Defendant's VCDs were coded with a unique NDC number, which allows for the identification and tracing of their product from manufacturer through the distribution chain to final dispensing to consumers. PELMC ¶¶ 177-179; PMMMC ¶¶ 144-146.

Were this not enough, "[i]n many cases, the 'Lot' number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate information including whether a recall applies to the particular pills in the bottle" PELMC ¶ 179; PMMMC ¶ 146. "The Lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events ('AE') (patient-specific side effects or complications associated with the use of a prescription drug)." PELMC ¶ 180; PMMMC ¶ 146. "A key part of the DSCSA [Drug Supply Chain Security Act] is the requirement that "product tracing information should be exchanged" for each transaction and retained for at least six years, including the following transaction information ("TI"):

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

PELMC ¶ 193; PMMMC ¶ 160.

The DSCSA adds an additional layer of identification and mandates the "use of a composite 'product identifier' that Manufacturer Defendants were required to begin applying to prescription drug packages and cases." PELMC ¶ 194; PMMMC ¶ 161. This is reflected in Defendants' own ordinary-course operations. For example, "[p]ublicly available Guidelines published by Defendant AmerisourceBergen require that 'each Prescription Drug lowest saleable unit' it receives from a manufacturer must have the clearly indicated product identifier on the unit label. In addition, case labels, and partial case labels must list the lot number and expiration date." PELMC ¶¶ 195-196; PMMMC ¶¶ 162-163.

The PELMC and PMMMC explain how the above sources of information kept in the ordinary course of business allow each Plaintiff or absent class member to identify who manufactured, distributed, or sold each VCD they purchased. In addition, for each named Plaintiff, the PELMC and PMMMC expressly allege the *specific* Manufacturer, Wholesaler, and Retail Pharmacy Defendant who made, distributed, or dispensed that Plaintiff's VCDs. For instance, the PELMC alleges for Plaintiff Borkowski:

> Plaintiff Alphonse Borkowski is a New York resident and citizen. During the class period Plaintiff Borkowski paid money for one or more of Defendants' VCDs, including purchases of VCDs manufactured, distributed, or sold by one or more ZHP Defendants (as defined infra Part II.C). This product ("ZHP Product") bore a unique NDC which denoted that it was indeed sold, manufactured, or distributed into the United States drug supply chain by the ZHP Defendants. Specifically, the ZHP Product that Plaintiff Borkowski purchased was manufactured by Defendant ZHP, and sold in the United States by Defendant Solco with the assistance of Defendant Huahai US and Defendant Prinston, who facilitated the regulatory approval of the ZHP product necessary for sale. At least some of this ZHP Product ultimately purchased by Plaintiff Borkowski was purchased from Defendant ZHP by Defendant McKesson who then distributed and resold that ZHP Product to Defendant Rite Aid (among other Retail Pharmacy Defendants). Defendant Rite Aid, in turn, sold the ZHP Product to Plaintiff Borkowski and other consumers. Each Defendant mentioned in this paragraph expressly and impliedly warranted to Plaintiff Borkowski (either directly, or indirectly by adopting warranties that were passed along to and incorporated by another Defendant further downstream and mentioned in this paragraph) that their respective generic VCDs were the same as

> their RLDs. But in fact, Plaintiff Borkowski purchased a product that was not the same to the RLD. Had Plaintiff Borkowski known the product was not the same as the RLD, Plaintiff Borkowski would not have paid for these Defendants' VCDs. Likewise, had these Defendants' deception about the impurities within their products been made known earlier, Plaintiff Borkowski would not have paid for these Defendants' VCDs.

PELMC ¶ 15. This allegation identifies who made the VCDs (ZHP), who distributed the VCDs (McKesson), and specifically who dispensed the VCDs (Rite Aid) to Mr. Borkowski. The PELMC and MMMC provide this detail for the other named consumer Plaintiffs. PELMC ¶¶ 14-58; PMMMC ¶¶ 396-412.[4] The PELMC also follows this pattern for TPP Plaintiffs by including illustrative data for their insureds and the VCDs for which TPP Plaintiffs reimbursed. *See* PELMC ¶¶ 59-72.

Unable to refute the factual reality that a wealth of product information and tracing data is maintained as part of the pharmaceutical industry's business operations, Defendants resort to arguing that because *each and every* VCD purchase by Plaintiffs is not traceable to *each* and *every* Defendant these claims are somehow not traceable at all. *See* Manuf. Br. at 11-13. Wholesaler Defendants and Retail Pharmacy Defendants further argue that each named Plaintiff must identify and trace, now at the pleadings stage, the exact product purchased at each and every sale over many years. *See* Wholesaler Br. at 5-13; Retail Pharmacy Br. at 25-26, 32-33. These arguments

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[4] The allegations are currently based on available information. Further discovery will reveal additional details for other VCD purchases by Plaintiffs. For instance, Plaintiffs sought inventory management and other tracing-related documents, including distribution agreements which will show which Wholesalers distributed which Manufacturers' VCDs to which Retail Pharmacies, from Wholesaler and Retail Pharmacy Defendants in December 2020. The Court did not order this discovery until June 10, 2021 (*see* ECF 1306); initial productions were not due until July 11, 2021 (*id.*); and these Defendants have until August 30, 2021 to substantially complete their productions (*id.*). By way of example, other discovery suggests Retail Pharmacy Defendant OptumRx's *only* had a contract with Wholesaler Defendant Cardinal Health for VCDs. This plausibly demonstrates that all the VCDs dispensed by OptumRx were distributed by Cardinal Health. At a minimum, Plaintiffs are entitled to prove this on the facts following discovery.

lack merit. The Court's order was clear: "in order to establish standing in the class action context, for each named defendant, *at least one* named plaintiff must be able to allege *an* injury traceable to that defendant." MTD Order No. 2 at 17 (emphasis added). The PELMC and PMMMC do this, and much more, thereby addressing the deficiencies outlined in MTD Opinion 2.

i. Class Plaintiffs' Claims Against Manufacturer Defendants Are Traceable

There is no legitimate dispute that Plaintiffs' injuries are traceable to the Manufacturer Defendants. Each Plaintiff now alleges the specific manufacturer(s) of their VCDs, based on unique NDC codes. Thus, each Plaintiff can and does "assert their own direct claim against a named Defendant." MTD Order No. 2 at 17 (emphasis added).

Manufacturer Defendants' purported concern that "many Defendants remain to whom no Plaintiff has traced an injury" misses the mark. For one, as alleged, these "many Defendants" comprise either affiliates of other named defendants,[5] or repackager/relabeler defendants subject to the order on dismissal without prejudice of so-called "peripheral" defendants.[6]

Second, this situation is no different than that in *Carlough v. Amchem Prod., Inc.*, which was an asbestos products liability case against multiple defendants. 834 F. Supp. 1437 (E.D. Pa. 1993). There, the plaintiffs had alleged that their injuries were the proximate result of exposure to the defendants' asbestos products. The court found that it was "clear that they have been exposed to asbestos, and it is clear that the CCR defendants manufactured asbestos and asbestos-containing products. Therefore, [the court] conclude[s] that plaintiffs have shown, for purposes of Article III standing, that their injuries are fairly *traceable* to the defendants' conduct." 834 F. Supp. at 1455

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[5] Arrow Pharma Malta Ltd. is an alleged manufacturing subsidiary of Teva. *See* PELMC ¶ 100; PMMMC ¶ 441. Torrent Pharma, Inc. and Torrent Pharmaceuticals, Ltd. are alleged subsidiaries of Torrent Pharma, Inc. *See* PELMC ¶¶ 103-105; PMMC ¶¶ 444-446.

[6] ECF 248.

(emphasis added). Plaintiffs been similarly exposed to Manufacturer Defendants' VCDs and the same principles of the traceability prong establishing Article III standing are met. Plaintiffs here have gone a step farther than the *Carlough* plaintiffs (a fact that is purposefully ignored by the Defendants) and have identified, by unique NDC number, which particular Manufacturer Defendants made Plaintiffs' VCDs.

ii. Class Plaintiffs' Claims Against Wholesaler Defendants Are Traceable

The Wholesaler Defendants argue that to meet the Article III standing requirement of traceability, each named Plaintiff must identify the exact product they purchased that any Wholesaler Defendant distributed.[7] This is neither the standard, nor consistent with the Court's earlier ruling. *See* MTD Order No. 2 at 16-17. At the pleading stage, an indirect causal connection is sufficient to establish standing as long as there is "a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000). "In the context of a class action, Article III must be satisfied by at least one named plaintiff." *Neale v. Volvo Cars of N. Am.*, 794 F.3d 353, 359 (3d Cir. 2015) (internal quotation omitted). Here, at least one named Medical Monitoring Plaintiff and at least one Economic Loss Plaintiff has tied their claims to each Wholesaler Defendant. That is enough.

Wholesaler Defendants assert that Plaintiffs must establish that *each* named Plaintiff has an injury traceable to *each* Wholesaler Defendant. *See* Wholesaler Br. at 6-7. Their argument is based on two points: first, that because some class representatives may not identify a specific wholesaler, they lack standing as to those wholesalers; and second, that Plaintiffs fail to meet the

[7] It is ironic that the Wholesaler Defendants are arguing that their own inadequate product tracing should be a credible basis for frustrating the Plaintiffs' claims.

traceability requirement because they do not identify the exact unit of contaminated valsartan distributed by each Wholesaler. Neither point withstands scrutiny.

There are the numerous named Plaintiffs who trace their injuries to one or more of Wholesaler Defendants.[8] For example, PMMMC Plaintiffs Judson and Daring, between the two of them, identify all three Wholesaler Defendants, and they by themselves satisfy class-wide Article III standing. *See* PMMMC at ¶¶ 397, 402, 500, 502-504.

That some new proposed named plaintiffs have yet to elicit facts to identify specific Wholesaler Defendants (*see* Wholesaler Br. at 5) is irrelevant to the question of whether the complaints sufficiently trace some injury to each Wholesaler Defendant. Moreover, the facts necessary to plead with this specificity were only revealed in Defense Fact Sheets, which have yet to be completed for newly proposed named plaintiffs. In essence, Wholesaler Defendants seek to dismiss claims on the basis that Plaintiffs have not adequately plead cognizable claims – when the information necessary to achieve the heightened pleading standard articulated by the Wholesaler Defendants is squarely within their own control. This reality alone demonstrates the futility of the Wholesaler Defendants' argument. That discovery revealed facts necessary for the many existing named plaintiffs identified above substantiates the prior allegations and temporary use of the "John Doe Wholesaler" allegations for new named plaintiffs.

Plaintiffs have plead that they purchased and/or consumed VCDs bearing the same NDC code as that distributed by each Wholesaler Defendant. Plaintiffs reviewed pharmacy records and

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[8] For instance, Plaintiffs Borkowski, Cacaccio, Semmel, Kaplan, Lee, Longwell, Mullins, Neal, Nelson, Wineinger, Judson, Zehr, and Kruk allege they purchased VCDs that were distributed by McKesson. PELMC ¶ 155; PMMMC ¶ 502. Plaintiffs Bruner, Duffy, Erwin, Mullins, Powell, Judson and Roberts allege they purchased VCDs that were distributed by AmerisourceBergen. PELMC ¶ 158; PMMMC ¶ 504. And Plaintiffs Gildner, Mullins, Daring, Silberman and Nelson allege they purchased VCDs that were distributed by Cardinal Health. PELMC ¶ 152; PMMMC ¶ 500.

the Defendant Fact Sheets provided by Wholesaler Defendants and have confirmed that each Wholesaler Defendant was responsible for distributing the batch of contaminated valsartan ultimately consumed by at least one named Plaintiff. PELMC ¶¶ 144-159; PMMMC ¶¶ 397-412. The Wholesaler Defendants' only dispute is that not *every* named Plaintiff identified the exact contaminated VCD unit that each Wholesaler Defendant distributed. This argument sidesteps the reality that the Plaintiffs' allegations at this stage need not establish proof of proximate causation. *See Powell Duffryn*, 913 F.2d at 72. Moreover, Plaintiffs' allegations as to common NDC codes, taken as true at this stage, make a sufficient showing that the contaminated VCDs they consumed can be fairly traced[9] to each Wholesaler Defendant.

iii. Class Plaintiffs' Claims Against Retail Pharmacy Defendants Are Traceable

The Retail Pharmacy Defendants make arguments similar to Manufacturer and Wholesaler Defendants, *viz.*, that each Plaintiff must trace each injury (i.e., each purchase of VCDs). But as discussed, the PELMC and PMMMC now allege which Plaintiffs purchased which VCDs at which retail pharmacies. This is enough. Plaintiffs need not allege, in item-by-item detail, each and every purchase from a retail pharmacy (especially when each such transaction will be reflected in Retail Pharmacy Defendants' own sales data). This satisfies the Court's MTD Order No. 2, as well as Third Circuit precedent.

2. Class Plaintiffs Have Standing to Bring Claims on Behalf of Absent Class Members

Defendants mistakenly argue that Article III standing must be assessed claim-by-claim at

[9] In their Motion, Defendants primarily rely on *Franklin*, but that case is distinguishable. In *Franklin*, the plaintiffs were unable to trace their injury from each of their 100 different mutual funds to the advisor and director defendants. 388 F. Supp. 2d at 456. Here, Plaintiffs' amended allegations link the unique NDC codes to each Wholesaler with at least one named Plaintiff.

the 12(b)(6) stage. Defendants then double-down and stake the position that not only must a class representative's standing be assessed on a defendant-by-defendant inquiry, but the standing should also be assessed on state-by-state inquiry. In so doing, Defendants essentially "mix up the class representative standing inquiry…[by] conflat[ing] the requirements of individual standing with those for a class representative." *Fox v. Ritz-Carlton Hotel Co.*, L.L.C., 977 F.3d 1039, 1047 (11th Cir. 2020). Indeed, "whether a plaintiff can bring a class action under the state laws of multiple states is a question of predominance under Rule 23(b)(3), not a question of standing under Article III." *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018).

A multi-state class action need not have a class representative from every possible state so long as the interests of class members from each state are aligned.[10] In the Third Circuit, "once threshold individual standing by the class representative is met, a proper party to raise a particular issue before the court, [] there remains no further separate class standing requirement in the constitutional sense." *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283, 306-07 (3d Cir. 1998) (emphasis supplied). PELMC and PMMMC Plaintiffs' burden at this stage is to establish standing for each claim, not for each state. PELMC and PMMMC Plaintiffs have met this burden.

i. Class Plaintiffs May Represent Absent Class Members From Other States Where a "False Conflict" of Laws Exist

Plaintiffs accept the Court's MTD Order No. 2 insofar as it held that a named plaintiff from State *X,* asserting claims under State *X*'s law for injuries sustained in State *X*, cannot assert claims

[10] *See, e.g., O'Neill v. Standard Homeopathic Co.*, 346 F. Supp. 3d 511 (S.D.N.Y. Sept. 28, 2018) (putative consumer class representatives had standing to assert claims related to products they themselves did not purchase); *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018) (named plaintiffs in certain states had standing to assert claims on behalf of absent class members in other states).

under State *Y*'s laws. For instance, Plaintiff Burnett, a North Carolina resident who bought and ingested VCDs in North Carolina, is only asserting claims under North Carolina law.

Plaintiffs' proposed amendments, however, present a different situation: that a named plaintiff of State *X* may represent persons from State *X*, *as well as* persons in states whose laws do not conflict with the laws of State *X*. *See* PELMC ¶ 607; PMMMC ¶ 560. This is consistent with *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985). In *Shutts*, the Supreme Court held that a class representative of one state may represent absent class members in different states provided there is a "false conflict" of law. *Id.* at 816 ("There can be no injury in applying Kansas law if it is not in conflict with that of any other jurisdiction connected to this suit."). The *Shutts* court remanded the matter for the lower courts to conduct a choice-of-law analysis.

Plaintiffs do not attempt to suggest to the Court that this inquiry should continue to be delayed in perpetuity. There is, indeed, a clear time in which courts routinely conduct an analyses of whether a "false conflict" exists – at the class certification stage. Countless cases in this District and Circuit hold this:

- *Rickman v. BMW of N. Am.*, No. CV 18-4363(KM)(JBC), 2020 WL 3468250, at *11 (D.N.J. June 25, 2020) (declining to address whether named plaintiff had standing to assert claims in under various state laws because the "more prudent approach would be to defer consideration of this argument until the certification stage… I here follow the lead of other cases that have declined to address similar issues in advance of class certification.")

- *Rolland v. Spark Energy LLC*, No. 17-2680, 2019 WL 1903990, at *5 n. 6 (D.N.J. Apr. 29, 2019) (rejecting the defendant's arguments that class representatives lacked standing to bring nationwide class claims under various states' laws on behalf of putative out-of-state class members as "unpersuasive" when denying a motion to dismiss).

- *Gress v. Freedom Mortg. Corp.*, 386 F. Supp. 3d 455, 462 (M.D. Pa. 2019) ("[p]laintiffs' capacity to state claims under the laws of other states on behalf of putative class members…is a matter to be decided under the rubric of Rule 23, not constitutional standing under Article III.")

- *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831, n. 56 (E.D. Pa. 2019) ("whether a plaintiff can bring a class action under the state laws of multiple states is a question of predominance under Rule 23(b)(3), not a question of standing") (internal quotations omitted).

- *In re FieldTurf Artificial Mktg. & Sales Prac. Litig.,* No. 17-2779, 2018 WL 4188459, at *8-9 (D.N.J. Aug. 31, 2018) (deferring choice-of-law analysis for putative nationwide class where no named plaintiff resided in 43 of 50 states).[11]

- *In re Liquid Aluminum Sulfate Antitrust Litig.*, No. 16-md-2687, 2017 WL 3131977, at *28 (D.N.J. July 20, 2017) (refusing to dismiss claims under Utah law where no named plaintiff resided in Utah).

- *In re Thalomid and Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 9589217, at * 19 (D.N.J. Oct. 29, 2015) ("attack on plaintiffs' standing to pursue state law claims on behalf of absent class members is not an Article III jurisdictional issue.")

- *Harper v. LG Elecs., USA, Inc.*, 595 F. Supp. 2d 486, 491 (D.N.J. 2009) (deferring choice of law analysis until after motion to dismiss, and for full factual record to be developed).

- *Ramirez v. STI Prepaid LLC*, 644 F. Supp. 2d 496, 505 (D.N.J. Mar. 18, 2009) (" the fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants' calling cards is immaterial").

- *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004) ("A choice of law analysis would be premature at this stage of the proceeding").[12]

The same is the norm in other sister Circuits.[13]

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[11] *See also In re FieldTurf*, 2018 WL 4188459, at *8-9 ("Prior to the class certification stage, it is premature to examine the named plaintiffs' standing to pursue claims on behalf of absent class members of the nationwide class . . .in states other than those in which they were injured," because that inquiry is one of "predominance [under Rule 23].").

[12] Courts outside this Circuit have also upheld the standing of named plaintiffs to bring claims on behalf of absent class members residing in other states.

[13] *See, e.g.*, *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018) ("whether a plaintiff can bring a class action under the state laws of multiple states, is a question of predominance under Rule 23(b)(3), not a question of standing under Article III."); *In re Opana ER Antritrust Litig.*, 162 F. Supp. 3d 704, 722 (N.D. Ill. 2016) ("Whether the named plaintiffs "may assert the rights of absent class members is neither a standing issue nor an Article III case or

Rickman, which is the most recent case in this District addressing this topic, cites to a string of authority justifying why claims brought by plaintiffs in states in which no named plaintiff resides should not be dismissed, deciding it was not a standing issue as Defendants assert, but rather a decision that should be deferred until the class certification stage. *See Rickman*, 2020 WL 3468250, at *11.[14] At a minimum, a choice-of-law analysis should be conducted on a separate, full record after the Rule 12 stage and before the Rule 23 stage. *See, e.g.*, *Amato v. Subaru of Am., Inc*., No. 18-16118, 2021 WL 21549876, at *5 (D.N.J. May 27, 2021); *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691 (D.N.J. 2011).

Plaintiffs' approach in the PELMC and PMMMC is not only consistent with the caselaw, but it also provides the most judicial efficiency. On a separate record, at or before class certification, the parties would have the opportunity to fully brief the choice-of-law question.[15] A

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controversy issue but depends rather on meeting the prerequisites of Rule 23 governing class actions."). *See, e.g.*, *Hoving v. Transnation Title Ins. Co.*, 545 F. Supp. 2d 662 (E.D. Mich. 2008) (upholding standing of eight represented states to bring claims on behalf of remaining states); *Jepson v. Ticor Title Ins. Co.*, No. C06-1723, 2007 WL 2060856, at *1 (W.D. Wash. May 1, 2007) (finding that a plaintiff could bring claims on behalf of absent class members residing in other states because "there [was] no question that the proposed class would have standing to assert [other states'] claims if it were certified."); *Pecanha v. The Hain Celestial Grp., Inc.*, 2018 WL 534299, at *9 (N.D. Cal. Jan. 24, 2018) (denying motion to dismiss and finding that standing to bring claims arising in other states could be deferred until certification).

[14] *See, e.g., Sheet Metal Workers Nat. Health Fund v. Amgen Inc.*, No. 07–5295, 2008 WL 3833577 at *9 (D.N.J. Aug.13, 2008) (declining to address argument that plaintiff lacks standing to bring claims under laws of states in which plaintiff failed to allege an injury and explaining that "because class certification creates the jurisdictional issue, the Court must treat the statutory standing issue before it deals with Article III standing, as instructed by Ortiz") (citing *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999)); *In re Hypodermic Prods. Antitrust Litig.*, No. 05-1602, 2007 WL 1959225 at *15 (D.N.J. June 29, 2007) (deferring consideration of argument that "Plaintiffs do not enjoy standing to raise state antitrust claims in jurisdictions in which they do not reside" until after class certification issues have been resolved); *Clark v. McDonald's Corp.*, 213 F.R.D. 198, 204 (D.N.J. 2003) (considering it appropriate to decide class certification before resolving Article III standing challenges where defendant had unpersuasively argued that "Clark does not enjoy standing to assert claims on behalf of class members regarding restaurants that Clark has not visited, or in states Clark has not visited").

[15] As these issues may relate to choice of law in the class certification context, "[a] court should

Rule 15 motion is not an appropriate vehicle to do so, especially when the Defendants in this litigation do not even mention choice-of-law in their 150 pages of briefing.[16] Further, this approach results in zero prejudice to Defendants, such as "expensive nationwide discovery," *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 223 (D.N.J. 2020), because document discovery is nationwide in this MDL, and is largely complete as "Phase I" discovery ended in June, with the exception of continuing discovery issues that are being litigated.

ii. Class TPP Plaintiffs Properly Allege Out-of-State Standing and Traceability

The TPP Plaintiffs (MADA and MSPRC) likewise have standing for purchases made by absent putative TPP class members. While Manufacturer Defendants argue that "MSPRC has alleged no factual basis to assert out-of-state claims under the laws of any state other than Connecticut, Ohio, and New York," and that "MADA has alleged no factual basis to assert out-of-state claims under the laws of any state other than Maine" (Manuf. Br. at 16), this Court has previously rejected a similar argument. *See In re Liquid Aluminum Sulfate Antitrust Litig.* No. CV 16-MD-2687 (JLL), 2017 WL 3131977, at *19 (D.N.J. July 20, 2017) ("[t]he Court also rejects Defendants' argument that the named IPP Plaintiffs lack standing to bring state law claims under the laws of a state in which they do not reside. As [plaintiffs] correctly note, the United States

exercise caution prior to class certification when asked to resolve choice-of-law questions in a nationwide class action where an array of factors beyond the residence of the class members must be considered, including the location of the parties and the purchased items." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 9589217, at *19 (D.N.J. Oct. 29, 2015) (Hayden, J.) (denying motion to dismiss and "defer[ing] its decision regarding the validity of any claims under particular state laws until the facts are further developed about the residence of putative class members or the state where they purchased or reimbursed their members for the price of Thalomid and Revlimid, and where the absent class members suffered an injury.").

[16] Arguably, Defendants' failure to even acknowledge the choice-of-law issue, as expressly pleaded in the PELMC and PMMMC, constitutes a waiver. *Williams v. BASF Catalysts LLC* 765 F.3d 306, 316 (3d Cir. 2014) ("All U.S. Courts of Appeals to have addressed the issue have held that choice-of-law issues may be waived.").

Supreme Court has made it clear that District Courts should defer addressing standing questions concerning putative class members who are not named until after class certification when certification of the class is "logically antecedent" to the issue of standing.") (citing *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 612 (1997)).

Just as the Consumer Plaintiffs are permitted under the law to assert claims on behalf of the unnamed putative class members at the Rule 12(b)(6) stage, so too are TPP Plaintiffs. *See In re Liquid Aluminum Sulfate Antitrust Litig.*, 2017 WL 3131977, at *28 (class representative asserted claims under Utah law *on behalf of* class members who were citizens or residents of Utah and made purchases in Utah, with the court finding that despite class representative not being citizens of Utah, that "[i]ndeed, allegations that members of the putative class *presumably include* Utah citizens and residents are sufficient to overcome a motion to dismiss indirect purchase[r]s claims under the Utah Antitrust Act when said allegations assert that said members of the putative classes made purchases in Utah.") (emphasis added) (internal quotations omitted).

D. Plaintiffs' Amendments Related to State Law Claims Are Not Futile

In the Court's orders regarding Defendants' previous motions to dismiss, the Court identified pleading issues related to a select number of Plaintiffs' state law claims against some of the Defendants. The Court further allowed Plaintiffs the opportunity to cure these deficiencies through pleading amendment.

In their proposed amendment, the Plaintiffs further clarified their pleadings in order to address and cure the deficiencies identified by the Court, and with these new amendments, Plaintiffs have now adequately plead cognizable state-law claims against each set of Defendants.

1. Plaintiffs' Amendments Adequately Plead Unjust Enrichment

MTD Order No. 6 dismissed without prejudice unjust enrichment claims in the ELMC only

as to 13 states, while permitting the balance of these claims to proceed under the other states' laws. *See* MTD Order No. 6 at 4. As to four of the dismissed-without-prejudice states - Florida, Iowa, Kansas, and Louisiana – the Court noted these states require "pleading no adequate remedy at law exists." *Id.* For nine of the states – Alabama, Florida, Hawaii, Idaho, Illinois, Louisiana, Massachusetts, Mississippi, Oklahoma, South Carolina, and West Virginia – the Court ruled that "plaintiffs must plead and are able to plead in these states that no adequate remedy at law exists." *Id.*

Plaintiffs corrected this in the PELMC, which explicitly pleads that "no adequate remedy at law exists." *See, e.g.*, PELMC at ¶¶ 776, 777, 784, 785. Nothing more is required. This Circuit has found language precisely such as this sufficient to comply with the obligation. *See In re Processed Egg Prod. Antitrust Litig.*, 851 F. Supp. 2d 867, 918 (E.D. Pa. 2012). Moreover, given the permissive nature of Fed. R. Civ. P. 8(d)(2) on alternative pleadings, other courts have found that they cannot rule, as a matter of law, that the technical wording of a complaint has failed to plausibly suggest that there was an absence of an adequate remedy at law. *See Fried v. JP Morgan Chase & Co.*, 850 F.3d 590, 604 (3d Cir. 2017) ("If the bar is not apparent on the face of the complaint, then it may not afford the basis for a dismissal of the complaint under Rule 12(b)(6).") (internal quotation marks, alterations and citation omitted); *see also Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) ("Technically, the Federal Rules of Civil Procedure require a defendant to plead an affirmative defense, like a statute of limitations defense, in the answer, not in a motion to dismiss.").

From a procedural standpoint, the Court previously ruled that Plaintiffs may plead unjust enrichment and other legal claims in the alternative. *See* MTD Order No. 6 (ECF 1019) at 28-29 ("The Restatement itself implies the alternative pleading of legal claims and an unjust enrichment

claim is permitted"). In the context of large MDLs such as this, Courts have routinely allowed complaints to plead both equitable and legal relief, finding that it would be premature to dismiss such claims with prejudice even if that Plaintiff may not ultimately recover under both theories. *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1259 (D.N.M. 2017); *see, also In re Dial Complete Marketing & Sales Practices Litig.,* 2013 WL 1222310, at *8-9 ("[C]onsistent with Federal Rules, Plaintiffs have simply plead their claims in the alternative ... the mere fact that plaintiffs have plead arguable inconsistent theories is not, standing alone, a sufficient basis to dismiss one of those claims."); *In re Light Cigarettes Marketing Sales Practices Litig.*, 751 F. Supp. 2d 183, 192 (D. Me. 2010) ("At this stage, the Plaintiffs may assert multiple and duplicative legal and equitable claims for relief."); *In re Celexa and Lexapro Marketing & Sales Practices Litig.*, 751 F. Supp. 2d 277, 297 (D. Mass. 2010) ("[I]t is inappropriate to dismiss equitable remedies at the pleading stage on this basis. Under the Federal Rules of Civil Procedure, plaintiffs have the prerogative to plead alternative and even conflicting theories*."); In re K–Dur Antitrust Litig.*, 338 F. Supp. 2d at 544 ("Plaintiffs, however, are clearly permitted to plead alternative theories of recovery. Consequently, it would be premature at this stage of the proceedings to dismiss the ... unjust enrichment claims on this basis.")

The question of whether there is an adequate remedy of law available to Plaintiffs is one that can only be decided after an application of the total discovery record to the law. The Federal Rules have accepted this necessity and provided that "relief in the alternative or of several different types may be demanded." Fed. R. Civ. P. 8(a). Defendants likewise benefit from this rule, as the rule further states that "a party may set forth two or more statements of a claim or defense alternately or hypothetically, either in one count or defense or in separate counts or defenses." Fed. R. Civ. P. 8(e)(2).

Moreover, Plaintiffs' alternative pleading is explicitly permitted under the law of Massachusetts, Illinois, Florida, Louisiana, Kansas and Alabama.

- ***Massachusetts*****:** In Massachusetts, "it is accepted practice to pursue both remedies at the pleading stage…although the Plaintiffs plead claims for both breach of contract and unjust enrichment, they plead these permissible in the alternative…The Plaintiffs' unjust enrichment claims therefore are not barred as a matter of law." *Durbeck v. Suffolk Univ.*, No. 20-10985, 2021 WL 2582621, at *11 (D. Mass. June 23, 2021) (quotation marks and intervening citations omitted). Illinois law "permits a party at the pleading stage to plead claims in the alternative, including pleading an unjust enrichment claim as an altearntive[.]" *Miller v. Lewis Univ.*, No. 20-C-5473, 2021 WL 1379488, at *6 (N.D. Ill. Apr. 12, 2021).

- ***Florida*****:** Under Florida law, a party may plead unjust enrichment in the alternative because, until a claim-at-law prevails, it cannot be said that an adequate remedy at law exists. *Gibson v. Lynn Univ., Inc.*, 504 F. Supp. 3d 1335, 1337 (S.D. Fla. 2020); *see also Lawrence v. FPA Villa Del Lago, LLC*, No. 8:20-cv-1517, 2021 WL 2401847, *3 (M.D. Fla. June 10, 2021).

- ***Louisiana*****:** Under Louisiana law, the provisions of La. Code Civ. Proc. Ann. art. 892 allow a plaintiff to assert inconsistent or mutually exclusive causes of action or defenses, so long as the allegations in his or her pleadings meet the following requirements: (1) well-grounded in fact, (2) warranted by existing law or a good faith argument for extension or change thereof, and (3) not plead for improper purposes. *See Alexis v. Metropolitan Life Ins. Co.*, 604 So. 2d 581 (La. 1992).

- ***Kansas*****:** In Kansas, an unjust enrichment claim can proceed forward until it is clear that another remedy exists which would preclude the alternate unjust enrichment theory. *See Ice Corp. v. Hamilton Sundstrand Inc.*, 444 F. Supp. 2d 1165, 1171 (D. Kan. 2006).

- ***Mississippi*****:** Mississippi allows plaintiffs, in their initial pleading document, to advance alternative and/or inconsistent claims. *See Jordan v. Wilson*, 5 So. 3d 442, 447 (Miss. Ct. App. 2008).

- ***Oklahoma*****:** Oklahoma law clearly permits pleading alternative remedies, just as it allows alternative theories of recovery, as long as plaintiffs are not given double recovery for the same injury." *See N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 929 P.2d 288, 295 (Okla. Civ. App. 1996).

- ***South Carolina:*** In South Carolina, courts frequently allow unjust enrichment claims to proceed in situations where such a claim relies on the same allegations to support contract-based claims, in the event such claims proved insufficient. *See King v. Carolina First Bank*, 26 F. Supp. 3d 510, 519 (D.S.C. 2014).

- ***Alabama*****:** Alabama courts have made clear that plaintiffs can plead both a remedy of law and an equitable remedy such as unjust enrichment "even though ultimately it will only be able to recover under one category of relief." *See Cajun Steamer Ventures, LLC v. Thompson*, 402 F. Supp. 3d 1328, 1350 (N.D. Ala. 2019).

- ***Hawaii*****:** Hawaii courts have made clear that alternative unjust enrichment claims can be perused when it is unclear at the 12(b)(6) stage whether a plaintiff has a "complete and adequate" remedy available to them. *See Jass v. Cherry Road Techs., Inc*., 472 F. Supp. 3d 787, 790 (D. Haw. 2020).

The Court should provide Plaintiffs with leave to amend their complaints to provide them with the opportunity to apply the full factual record to the law and determine whether Unjust Enrichment is a remedy they may ultimately be the only remedy available to them.

2. Plaintiffs' Amendments Adequately Plead Express Warranty

MTD Order No. 3 addressed warranty claims including both express and implied warranty claims in all three (3) of the Master Complaints. Manufacturer Defendants no longer challenge the warranty claims, only the Wholesaler and Retail Pharmacy Defendants do so.

i. Plaintiffs' Amendments as to Wholesaler Defendants Adequately Plead Express Warranty Claims

In response to the Court's MTD Order No. 3, Plaintiffs have re-pleaded claims against the Wholesaler Defendants that allege both a basis of the bargain and privity in each of the Master Complaints. The lack of an agreement specifically between Wholesaler Defendants and consumers and TPPs is certainly not determinative of the existence of a warranty claim. Specifically, Plaintiffs and class members allege they are the "intended third-party beneficiary recipients" of certain contracts or agreements to which wholesalers are parties that provide warranties pertaining to the VCDs' non-adulterated and FDCA-compliant status. *See, e.g.*,PELMC ¶¶ 236, 651-52 (consumer implied warranties economic loss claim), ¶¶ 666-67 (TPP implied warranties economic loss claim), PMMMC ¶¶ 190, 645-46 (medical monitoring implied warranty claim).)

In addition, Plaintiffs allege in more detail exactly how the Wholesaler Defendants transfer

custody of VCDs and the warranties they make during these transfers. As alleged in the Master Complaints, "[w]hen Wholesaler Defendants receive shipments of VCDs, they distribute these shipments into smaller pallets sometimes referred to as "totes," which are then sent to the Pharmacy Defendants." PELMC ¶ 507. The Wholesaler Defendants are also required to prepare as part of their obligations under the DSCSA certain "electronic records or manifest[s], in which the Wholesaler Defendants warrant that the tote contains a certain product." *Id*. at ¶ 508. Those warranties accompanying the totes are express warranties made downstream including but not limited to consumers and TPPs. *Id*. at ¶ 511-513.

For each of the Wholesaler Defendants, Plaintiffs make further defendant-specific allegations. *See, e.g*., PELMC ¶¶ 522-535 (McKesson), ¶¶ 536-547 (Cardinal), ¶¶ 548-555 (AmerisourceBergen). For example, Defendant McKesson received an FDA warning letter for non-compliance with the DSCSA pertaining to a 2018 inspection of its corporate headquarters. That warning letter found that McKesson had failed to put in place procedures that complied with the DSCSA including with regard to identifying and/or quarantining suspect or illegitimate products such as the adulterated VCDs. PELMC ¶¶ 528-531. This is despite the fact that McKesson loudly and publicly proclaims compliance with such laws and regulations. *Id.*

ii. Plaintiffs' Amendments as to the Retail Pharmacy Defendants Adequately Plead Express Warranty Claims

The Court dismissed the Plaintiffs' express warranty claims against the Retail Pharmacy Defendants without prejudice. MTD Order No. 3 at 3. In the Plaintiffs' Proposed Amended Master Complaints, Plaintiffs re-plead viable express warranty claims against the Retail Pharmacy Defendants.

Privity is clearly alleged and present as between consumers and the Retail Pharmacy Defendants because there is a direct buyer/seller relationship when a consumer purchases a VCD

from a Retail Pharmacy Defendant. PELMC ¶ 106 ("The retail pharmacy defendants stand in direct contractual privity with consumers ...."); *id.* ¶ 461 ("Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract."). Those allegations should be accepted as true and are not disputed by the Retail Pharmacy Defendants in their brief opposing the motion to amend.

As for the substance of express warranties, the proposed amended Master Complaints all allege that the Retailer Pharmacy Defendants expressly warrant that the pharmaceuticals they offer "are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics." PELMC ¶ 462. The Complaints further allege that "[m]ore generally, Retail Pharmacy Defendants warrant that prescription drugs they sell are of a standard quality." *Id.*

The proposed amended complaints go even further by alleging specific statements constituting express warranties on the part of various Retail Pharmacy Defendants, including CVS (PELMC ¶¶ 556-565), Walgreens (*id.*, at ¶¶ 566-576), Rite-Aid (*id.*, at ¶¶ 577-583), and Walmart (*id*. at ¶¶ 584-596).

The allegations as set forth in the complaint are certainly sufficient to put the Retail Pharmacy Defendants on notice of the express warranty claims alleged by consumers against them. Further, discovery against the Retail Pharmacy Defendants will yield further information to support the allegations set forth in the proposed master complaints.

3. Plaintiffs' Amendments Adequately Plead Implied Warranties

i. Determining the Existence of Privity Requires a Full Factual Record

For purposes of amendment, whether Plaintiffs' breach of implied warranty claims require privity in certain states rests on various unsettled ambiguities contained in each state's laws. This

is, in fact, precisely why courts have concluded that privity is a question of fact that is ill-suited for resolution at the motion to dismiss or motion for leave to amend stage. *See, e.g., Baranco v. Ford Motor Co.*, 294 F. Supp. 3d 950, 975 (N.D. Cal. 2018) ("The scope of that agency relationship (and hence privity) is a question of fact."); *cf. In re MyFord Touch*, 46 F.Supp.3d 936, 956 (N.D. Cal. 2014) (holding that the scope of the agency is a factual one for the jury to resolve)); *Dewey v. Volkswagen AG*, 558 F. Supp. 2d 505, 524, n. 17 (D.N.J. 2008) ("The Court finds that the issue of privity between the Defendants and the seller of Romeo's automobile involves issues of fact not appropriate for resolution at the motion to dismiss stage."); *MacMorris v. Wyeth*, No. 2:04-CV-596-FTM-29-DNF, 2005 WL 1528626, at *3 (M.D. Fla. June 27, 2005) (the court declined to determine whether privity would fail in a products liability suit against a drug manufacturer at the motion to dismiss stage, holding that it was not an appropriate determination: "At the motion to dismiss stage the Court cannot determine that privity will fail in this case. The motions will be denied"). Thus, it is still too early for the Court to make such a decision, and the PPIMC, PELMC, and PMMMC should be allowed to go forward with the proposed amendments.

1. Plaintiffs' Amendments Adequately Plead Implied Warranty Claims Under Kentucky

Manufacturer and Wholesaler Defendants argue that lack of privity dooms Plaintiffs' Kentucky breach implied warranty claims. *See* Manuf. Br. at 19; Wholesaler Br. at 20. However, for purposes of amendment, the factual record set forth in the complaint is such that when applied to the ambiguity in the current state of the law, it would be inappropriate for the Court to dismiss the claims at this stage.

The Kentucky Supreme Court addressed the privity requirement in *Griffin Industries, Inc. v. Jones*, 975 S.W.2d 100 (Ky. 1998). In that matter the Court clearly stated that "privity is not a prerequisite to the maintenance of an action for breach of an implied warranty in

products liability actions." *Id*. at 102. The court ruled that Kentucky adopted section 402A of the Restatement (Second) of Torts in *Dealers Transport Co., Inc. v. Battery Distributing Co., Inc.*, 402 S.W.2d 441 (Ky.1965). According to the 1998 Kentucky Supreme Court in *Griffin*,

> ...[i]n *Dealers supra,* the court held that privity is not a prerequisite to the maintenance of an action for breach of an implied warranty in products liability actions. Since that time there have been numerous cases recognizing that theory of recovery in product liability cases. (*Id.*, at 102).

Unfortunately, just eight (8) years later, the very same Court added to the confusion in *Compex International v. Taylor*, 209 S.W.3d 462 (Ky. 2006), which Manufacturer Defendants cite in their Brief, along with *Simpson* (Manuf. Br. at 20) when it reversed course. Accordingly, Plaintiffs respectfully submit that the common law on this issue in Kentucky is still ambiguous and ruling be reserved until after further discovery and evidence.[17]

2. Implied Warranty Claims Under Wisconsin Law

Plaintiffs have removed the Wisconsin implied warranty claim from the proposed amended master complaints.

ii. Plaintiffs' Amendments Adequately Plead Implied Warranty Claims as to the Manufacturer Defendants

All states and territories listed in the PELMC and PMMMC recognize implied warranty claims for merchantability and fitness. Manufacturer Defendants' VCDs have been alleged to be

[17] *See In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, No. 2:19-MD-2921-BRM-ESK, 2021 WL 1050910, at *42 (D.N.J. Mar. 19, 2021) ("[P]rivity of contract does not extend beyond the buyer-seller setting, and an intervening purchaser destroys privity." *Id.* (citations omitted). However, "an actual and direct promise for the benefit of a third party will be sufficient to create privity between the promisor and the third-party beneficiary." *Louisville Gas & Elec. Co. v. Continental Field Systems, Inc.*, 420 F. Supp. 2d 764, 770 (W.D. Ky. 2005) (citations omitted). Here, whether an individual Plaintiff may establish a third-party beneficiary status will not be scrutinized at this stage, meaning Plaintiffs may proceed with an implied warranty claim.").

non-merchantable and unfit in the most obvious sense of the terms; it was unlawful for Defendants to sell drugs contaminated with nitrosamines and place the VCDs at issue herein into the stream of commerce (*i.e*., distribute, sell, dispense in the United States) because Congress has determined that adulterated pharmaceuticals are non-merchantable and unfit for any use. *See* 21 U.S.C. § 331, 351. It is actually illegal to introduce an adulterated or misbranded drug into interstate commerce. 21 U.S.C. § 331(a). The following are examples of where courts have found exceptions to the privity requirement, further indicating that these determinations are questions of fact that cannot be resolved at the motion to amend or motion to dismiss stages.

- ***Alabama***: Under Alabama law, "a vertical nonprivity purchaser who has suffered only economic loss can recover from a remote seller or manufacturer under a theory that the purchaser is a third-party beneficiary of a contract containing the manufacturer's express warranty to a dealer or an intermediate seller." *Harris Moran Seed Co. v. Phillips*, 949 So. 2d 916, 923 (Ala. Civ. App. 2006) (stating that under Alabama law) (citing *Bay Lines, Inc. v. Stoughton Trailers, Inc.*, 838 So.2d 1013 (Ala.2002))).

- ***Arizona***: Under Arizona law, "[n]o privity of contract is needed to recover for physical injuries under the theory of strict liability in tort." *Flory v. Silvercrest Indus., Inc.*, 129 Ariz. 574, 579, 633 P.2d 383, 388 (1981). Further, there may be instances in which there is a "potential for danger to person property" where privity may be waived. *See Miidas Greenhouses, LLC v. Glob. Horticultural, Inc.*, 226 Ariz. 142, 145-1466, 244 P.3d 579, 583 (Ct. App. 2010)

- ***Idaho***: Under Idaho law, "the Idaho Supreme Court held that a plaintiff may pursue UCC breach of warranty claims for personal injuries only if …the plaintiff qualifies as a third-party beneficiary of the underlying sales contract." *Corbett v. Remington Arms Co., LLC*, No. 4:15-CV-00279-BLW, 2016 WL 1755456, at *2 (D. Idaho May 2, 2016).

- ***Iowa***: Manufacturing Defendants do not address Iowa's privity requirement in their Brief. However, Iowa law abolished privity as to personal injury, and leaves it open as to whether it is even needed for solely economic injuries. *Tomka v. Hoechst Celanese Corp.*, 528 N.W.2d 103, 108 (Iowa 1995) (emphasis added) (leaving open whether privity is required for breach of implied warranties seeking only direct damages); *see Klingenberg v. Vulcan Ladder USA, LLC*, No. 15-CV-4012-KEM, 2018 WL 1248007, at *12 (N.D. Iowa Mar. 9, 2018), *aff'd*, 936 F.3d 824 (8th Cir. 2019) ("Thus, Iowa Code section 554.2318 abolishes privity as a defense when a defective product causes "personal injury or property damage"); *see also* Iowa Code Ann. § 554.2318 ("A seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume or be

affected by the goods and who is injured by breach of the warranty. A seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty extends.").

- ***Kansas*:** Under Kansas law implied warranties extend to persons "who suffer personal, as opposed to economic, injury," where privity is not required. *Limestone Farms, Inc. v. Deere & Co.*, 29 P.3d 457, 461 (Kan. Ct. App. 2001). The Kansas Supreme Court in *Professional Lens Plan, Inc. v. Polaris Leasing Corp.,* held that "implied warranties of fitness and merchantability are not extended to a remote seller or manufacturer *of an allegedly defective product, which is not inherently dangerous*, for only economic loss, suffered by a buyer who is not in contractual privity with the remote seller or manufacturer." 675 P.2d 887, 898–99 (Kan.1984) (emphasis added). However, the products here are clearly "inherently dangerous" (*i.e.* the contaminated VCDs), and thus Plaintiffs should be able to recover for economic damages due to the inherently dangerous nature of the VCDs.

- ***Michigan*:** Manufacturing Defendants do not address Michigan's privity requirement in their Brief. Under Michigan law, the Sixth Circuit has "conclude[d] that Michigan has abandoned the privity requirement for implied-warranty claims." *Pack v. Damon Corp.*, 434 F.3d 810, 820 (6th Cir. 2006); *see also In re: Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, No. 2:19-MD-2921-BRM-ESK, 2021 WL 1050910, at *42 (D.N.J. Mar. 19, 2021) ("The Court finds Michigan allows an implied warranty claim asserted against medical products.").

- ***North Carolina*:** Under North Carolina law courts have found a privity exception for implied warranty claims where the plaintiff is an alleged third-party beneficiary. *See Coastal Leasing Corp. v. O'Neal*, 103 N.C.App. 230, 405 S.E.2d 208 (1991) (f); *see also LSB Fin. Servs. v. Harrison*, 144 N.C.App. 542, 548, 548 S.E.2d 574, 579 (2001); *Murray v. Nationwide Mut. Ins. Co.*, 123 N.C.App. 1, 15, 472 S.E.2d 358, 366 (1996).

- ***Ohio***: Under Ohio law, courts have found that an end consumer has "privity of contract with the manufacturer if that consumer is an intended third-party beneficiary to a contract... one for whose benefit a promise is made, but who is not a party to the contract encompassing the promise" and concluding "...then that third party is an 'intended beneficiary' who has enforceable rights under the contract. " *Bobb Forest Products, Inc. v. Morbark Industries, Inc.*, 151 Ohio App.3d 63, 84, 783 N.E.2d 560, 576 (2002).[18]

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[18] *See In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, 2021 WL 1050910, at *44 ("[T]o sustain a contract-based breach of implied warranty claim, the parties must be in privity." *Caterpillar Fin. Servs. Corp. v. Harold Tatman & Son's, Enters.*, 50 N.E.3d 955, 962 (Ohio Ct. App. 2015). But "when the manufacturer is so involved in the sales transaction that the distributor merely becomes the agent of the manufacturer, then the manufacturer and the ultimate consumer are in privity of contract." *Bobb Forest Prods., Inc. v. Morbark Indus. Inc.*, 151 Ohio App.3d 63, 783 N.E.2d 560, 576 (Ohio Ct. App. 2002) (citations omitted). "A consumer may also have privity of contract with the manufacturer if that consumer is an intended third-party

- ***Tennessee***: Under Tennessee law, "[i]n all causes of action for personal injury or property damage brought on account of… breach of warranty, including actions brought under the provisions of the Uniform Commercial Code, privity shall not be a requirement to maintain said action." *Turnage v. Oldham*, 346 F. Supp. 3d 1141, 1157 (W.D. Tenn. 2018) (citing Tenn. Code Ann. § 29-34-104).[19]

- ***Utah***: Under Utah law, courts have found "it would be unjust to recognize a rule that would permit manufacturers of goods to represent that goods possess qualities they do not possess, and then deny the customer to recover damages because there is no privity of contract existing between the consumer and the manufacturer." *Stembridge v. Nat'l Feeds Inc.*, No. 1:11CV49DAK, 2013 WL 5347455, at *6 (D. Utah Sept. 23, 2013).

The Manufacturer Defendants continually fail to acknowledge that many states will find privity for purposes of implied warranty claims under a number of different circumstances described above, including but not limited to, under a third-party beneficiary theory, applicable factually to this case. At minimum, the applicability of these privity exceptions is a fact question that cannot be resolved at this stage.

iii. Plaintiffs' Amendments Adequately Plead Implied Warranty Claims as to the Wholesaler Defendants

Wholesaler Defendants are liable for any implied warranties based on indemnification agreements alleged to exist, as well as on agency principles of liability.[20] The same reasoning applies as to why Plaintiffs have properly alleged breach of implied warranty claims against the

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beneficiary to a contract." *Id.* at 84 (citations omitted).

[19] *See In re: Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, 2021 WL 1050910, at *45 ("[t]he Tennessee General Assembly abolished the requirement of privity on April 10, 1972." *Travelers Indem. Co. v. Indus. Paper & Packaging Corp.*, No. 3:02-CV-491, 2006 WL 2050686 at *8(E.D. Tenn. July 19, 2006). "The legislation enacted provides that in all cases of action for personal injury or property damage brought on account of ... breach of warranty, privity shall not be a requirement to maintain said action." *Id.* (citing T.C.A. § 29-34-104).").

[20] *See, e.g.*, *Geraczynski v. Nat'l R.R. Passenger Corp.*, No. 11-6385, 2015 WL 4623466 (D.N.J. July 31, 2015) ("Indemnity is required not only as a matter of contract but also as a matter of common law, which requires a product distributor to indemnify other distributors and sellers further down the chain of distribution, with the ultimate responsibility for losses caused by product defect resting at the top of the chain with the manufacturer."). This is a fact question not amenable to dismissal on a Rule 12 or Rule 15 motion.

Manufacturer Defendants as to the Wholesaler Defendants. Furthermore, the Wholesaler Defendants also fail to acknowledge that many states will find privity under a number of different circumstances including a third-party beneficiary theory. The following are examples of where courts have found exceptions to the privity requirement, further indicating the fluidity of the case law and why these are fact determinations that cannot be resolved at this stage.[21]

- ***Connecticut***: Under Connecticut law, "the general rule requiring privity is subject to certain limited exceptions." *Kahn v. Volkswagen of Am., Inc.*, 2008 WL 590469, at *8 (Conn. Super. Ct. Feb. 13, 2008). In *Kahn* the court found that after reviewing developments in Connecticut law, District Judge Clarie held that the "privity requirement is not etched in stone and the doctrine is only applied to situations in which alternative remedies that do not require privity are available." *Id. (*citing *Utica Mutual Ins. Co. v. Denwat Corp.,* 778 F.Supp. 592, 595–96 (D.Conn.1991)). Further, courts applying Connecticut law have also recognized that it may be possible to satisfy the privity requirement by pleading facts which establish an agency relationship (i.e. between a vehicle manufacturer and dealership). *Id.*

- ***Georgia***: Under Georgia law, if the manufacturer expressly warrants to the ultimate consumer that the product will perform in a certain way or that it meets particular standards, privity with that ultimate consumer is deemed to exist." *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011). "Thus, where the manufacturer extends an express warranty to the end consumer, privity is created that satisfies the requirements of the implied warranty of merchantability." *Hemmings v. Camping Time RV Centers, LLC*, No. 1:17-CV-1331-TWT, 2017 WL 4552896, at *6 (N.D. Ga. Oct. 11, 2017).

- ***Illinois***: Under Illinois law, courts have recognized an exception to the privity requirement in situations when buyer who has sustained personal injuries predicates recovery against a remote manufacturer for a breach of implied warranty." *Wheeler v. Sunbelt Tool Co.*, 181 Ill. App. 3d 1088, 1099, 537 N.E.2d 1332, 1340 (1989).

[21] *See, e.g, In re Subaru Battery Drain Prod. Liab. Litig.*, No. 1:20-CV-03095-JHR-JS, 2021 WL 1207791, at *17 (D.N.J. Mar. 31, 2021) (With respect to New York law, courts have found that the privity analysis is too fact intensive to resolve at the motion to dismiss stage where Plaintiffs plead a third-party beneficiary relationship…Because Plaintiffs have alleged that they are "third-party beneficiaries of contracts between Subaru and its dealers, and specifically Subaru's implied warranties," the Court will deny Defendants' motion as to Plaintiffs […] and […]'s implied warranty claims.); *Argabright v. Rheem Mfg. Co.*, 258 F. Supp. 3d 470, 487 (D.N.J. 2017) ("The Court finds that the issue of privity between the Defendants and the seller of Romeo's automobile involves issues of fact not appropriate for resolution at the motion to dismiss stage. Defendants may renew this argument on a motion for summary judgment if they choose.").

- ***New York:*** Under New York law, "there is no requirement of privity for [an implied] warranty claim so long as the plaintiff's claim is one for personal injury." *In re: Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, No. 2:19-MD-2921-BRM-ESK, 2021 WL 1050910, at *43 (D.N.J. Mar. 19, 2021) (citing *Mahoney v. Endo Health Solutions, Inc.*, No. 15cv9841(DLC), 2016 WL 3951185 at *5 (S.D.N.Y. July 20, 2016)); *see In re Subaru Battery Drain Prod. Liab. Litig.*, No. 1:20-CV-03095-JHR-JS, 2021 WL 1207791, at *17 (D.N.J. Mar. 31, 2021) ("With respect to New York law, courts have found that the privity analysis is too fact intensive to resolve at the motion to dismiss stage where Plaintiffs plead a third-party beneficiary relationship.").

iv. Plaintiffs' Amendments Adequately Plead Implied Warranty Claims as to the Retail Pharmacy Defendants

What the Retail Pharmacy Defendants purposefully ignore is that the privity of implied warranties is most clearly established between the consumers/purchasers of the VCDs and the Retail Pharmacy Defendants. Retail Pharmacy Defendants are acutely aware that they have the direct seller-buyer relationship with the Plaintiffs. Because direct privity exists between the Retail Pharmacy Defendants and the Plaintiffs(as well as the implied warranties such transactions carry), the Retail Pharmacy Defendants are only left to argue, in conclusory fashion, that they are so called "innocent sellers." However, the question of whether a party is an innocent seller is a highly fact specific inquiry that is subject to a handful of state innocent seller defenses and exceptions (such as the inability to collect a judgment from a manufacturer), would ultimately preclude or permit claims.

As much as the Retail Pharmacy Defendants wish to depict the law as being uniform in absolving them from liability, the reality is far from that. While it is true that some states have enacted statutes limiting strict liability to innocent sellers, the PIMC alleges, as explained above, that Retail Pharmacy Defendants knew or should have known of the defect and yet did nothing; moreover, most innocent seller statutes contain exceptions permitting liability to attach such as where the manufacturer of the product cannot be identified, where there are jurisdictional issues, or where there may be potential insolvency of other defendants or an inability to collect a

judgment.[22] It is axiomatic that these exceptions cannot be ruled as inapplicable in absence of full discovery. *See, e.g.*, *Thomas v. Firerock Prods., LLC*, 40 F. Supp. 3d 783, 792 (N.D. Miss. 2014) (denying motion to dismiss on basis of innocent seller affirmative defense because elements not obviously met on face of complaint); *Fahy v. Taser Int'l, Inc.*, No. 4:10-cv-19, 2010 WL 559249, at *2 (E.D. Mo. Feb. 10, 2020) (Missouri's innocent seller statute "does not affect a defendant's potential liability to a plaintiff at the pleadings stage"); *Geraczynski v. National R. R. Passenger Corp*, 2013 WL 5934552, at *4 (D.N.J. Nov. 1, 2013) (only ruling on innocent seller defense at summary judgment after discovery.

With respect to specific state law claims, the Retail Pharmacy Defendants argue that Plaintiffs' breach of implied warranty claims arising under the laws of Oklahoma and Utah are futile by regurgitating the same arguments the Court previously rejected in ruling on the Retail Pharmacy Defendants' Motion to Dismiss. Specifically, Defendants allege that Plaintiffs cannot maintain breach of implied warranties under the laws of these states, relying on case law based on failure to warn issues, rather than implied warranty claims. *See* Retail Pharmacy Br. at 45.

For example, with respect to Plaintiffs' Oklahoma claims, the Retail Pharmacy Defendants cite *White v. Mylan, Inc.*, No. Civ-12-402-D, 2012 WL 6726953 (W.D. Okla. Dec. 27, 2012), an unpublished district court case that does not reference warranty claims at all. *See* Retail Pharmacy Br. at 45. Instead, the *White* court addressed the applicability of the learned intermediary doctrine

[22] *See, e.g.,* Ala. Code § 6–5–521(c); *see also, e.g.,* D.C.A. tit. 18 §7001 (Delaware); Ind. Code § 34-20-2-4; Iowa Code Ann. § 613.18; Kansas Stat. 60-3306 (Kansas); KRS 411.340 (Kentucky); Md. Code Ann., Cts. & Jud. Proc. § 5-405; Minn. Stat. § 544.41 (Minnesota); Mo. Ann. Stat. § 537.762 (Missouri); N.J. Stat. § 2A:58C-2 (New Jersey); N.C.G.S.A. § 99B-2(a) (North Carolina); N.D. Cent. Code § 28-01.3-04 (North Dakota); O.R.C. 2307.78(B) (Ohio); Okla. Stat. tit. 76, § 52.2.E (Oklahoma); Tenn. Code Ann. §29-28-106 (Tennessee); Texas CPRC Sec. 82.003(a)(7); Wis. Stat. § 895.047 (Wisconsin).

to strict liability failure to warn claims. *Id.* at *4. With respect to Plaintiffs' Utah claims, the Retail Pharmacy Defendants cite *Shaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922 (Utah 2003), which again does not reference implied warranty claims. Instead, the *Shaerrer* court also addressed strict liability failure to warn claims. *Id.* at 929.

The Court should apply the same standard as it did when it ruled on the Retail Pharmacy Defendants' previous 12(b)(6) briefing. MTD Order No. 3, at 23. When examining the Retail Pharmacy Defendants' argument, the Court closely reviewed the cited cases in order to apply the "recommended liberality" to implied warranty claims. *Id.* The Court specifically looked for "any jurisdiction where the Pharmacies' assertions likely did not apply or where the law was as yet unclear" such as "any case that either relied on a strict liability-failure to warn theory." *Id.* In essence, the Court analyzed cases like *White* and *Shaerrer* for the express purpose of excluding those cases from its decision-making process. As was the case when the Retail Pharmacy Defendants brought their Motion to Dismiss, cases like *White* and *Shaerrer*, which do not address the availability of a cause of action for breach of implied warranty and are limited to discussion of failure to warn claims, are inapposite. Defendants failed to cite to any of Plaintiffs' proposed amendments that address the arguments the Court previously analyzed and rejected.

Because the law regarding breach of implied warranty claims as applicable to pharmacies is not settled in either Oklahoma or Utah the Court should apply the "recommended liberality," for Plaintiffs' breach of implied warranty claims arising under the laws of Oklahoma and Utah and grant Plaintiffs leave to amend the PIMC. MTD Order No. 3, at 23

4. Plaintiffs' Amendments Adequately Plead Negligence

The majority of Plaintiffs proposed amendments include added allegations as to the

negligence of the Wholesaler[23] and Retail Pharmacy Defendants. Not only are these amendments[24] not futile, but, taken at their face, they raise cognizable negligence claims against the Wholesaler and Retail Pharmacy Defendants.

The Wholesaler Defendants and Retail Pharmacy Defendants are liable for negligence claims if the allegations demonstrate they breached their common law duties to appropriately vet their generic manufacturer suppliers to ensure that they did not sell adulterated, misbranded and/or contaminated product. *See, e.g.*, *Cherokee Nation v. McKesson Corp.*, 2021 WL 1200093, at *8 (E.D. Okla. Mar. 29, 2021) (rejecting innocent seller defense to negligence claim, argued by many of the same Wholesaler and Retail Pharmacy Defendants here, and finding those same Defendants owed duty under state negligence theory). As Courts have previously held, whether it is reasonably foreseeable that a wholesaler's or retailer's distribution practices would result in the sale of adulterated or misbranded drugs is ultimately "a question of fact which cannot be determined at the pleading stage." *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 211 (E.D.N.Y. 2004) (denying a negligence claim against AmerisourceBergen for the sale of misbranded drug); *see also, e.g.*, *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, MDL No., 13-02419, 2015 WL 178130, at *3 (D. Mass. Jan. 13, 2015) (denying pharmacy's motion to dismiss negligence claim where, as here, pharmacy allegedly failed to exercise reasonable care "to ensure that the drugs they purchased and provide to plaintiffs were made and sold in compliance with all applicable pharmaceuticals laws...fail[e]d to follow certain policies and procedures to ensure such drugs were safe…and generally fail[ed] to ensure they were not injecting contaminated and

[23] Manufacturer Defendants do not challenge the negligence claims in any proposed amended complaint, only Wholesalers and Retail Pharmacy Defendants do.

[24] The Court's MTD Order No. 5 directed the Plaintiffs to allege more information about Wholesaler and Retail Pharmacy Defendants' alleged duties.

dangerous drugs into their patients”).

i. Plaintiffs’ Amendments Plead Cognizable Negligence Claims Against Wholesaler Defendants

The proposed amended complaints allege that each Wholesaler Defendant, specifically, acted “as the intermediary between the Manufacturer Defendants and the Retail Pharmacy Defendants.” PELMC ¶ 145. Each Wholesaler Defendant contracted with Manufacturer Defendants for the purchase of VCDs, and with Retail Pharmacy Defendants for the sale of VCDs. Plaintiffs also explicitly allege that “[a]t all times, Plaintiffs, as the purchasers of VCDs, were the intended beneficiaries of the contracts.” PELMC ¶ 148.

For instance, Cardinal Health distributed VCDs manufactured by all Manufacturer Defendants which were ultimately sold to Plaintiff Gildner, Nelson, and other similarly situated consumers. PELMC ¶¶ 150-152. McKesson distributed VCDs manufactured by all Manufacturer Defendants which were ultimately sold to Plaintiffs Borkowski, Cacaccio, Semmel, Kaplan, Lee, Longwell, Neal, Nelson, Wineinger, and other similarly situated consumers. PELMC ¶¶ 153-155. AmerisourceBergen distributed VCDs manufactured by all Manufacturer Defendants, which were ultimately sold to Plaintiffs Bruner, Duffy, Erwin, Powell, Roberts and other similarly situated consumers. PELMC ¶¶ 156-159.

The Amended Complaints allege that each Wholesaler Defendant had a duty to “confirm the quality, purity, generic equivalence, therapeutic equivalence, or bioequivalence of the contaminated, adulterated and/or misbranded VCDs.” PELMC ¶ 144.

The Amended Complaints further describe in detail each Wholesaler Defendant’s duties relating to the Drug Supply Chain Security Act (DSCSA). *See, e.g.*, PELMC ¶¶ 181-196; 468-513. As a participant in the pharmaceutical drug supply chain, each Wholesaler Defendant had a duty to ensure they did not introduce into the stream of commerce adulterated, misbranded, or

illegitimate product. *Id*. Each Wholesaler Defendant, for instance, was required to "develop verification methods to determine whether a product is valid, suspect or illegitimate product." PELMC ¶ 4. Each Wholesaler was obligated to comply with cGMPs as well as Good Distribution Practices ("GDPs"). PELMC ¶ 492. One aspect of GDPs is the implementation of strong quality management systems. PELMC ¶ 493.

This obligation did not end upon confirmation that a pharmaceutical supplier was manufacturing product in a facility that had been approved by a regulatory body. Indeed, Good Distributor Practices dictate that: "**Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products.** PELMC ¶¶ 491-503 (emphasis added). **The quality system should be developed and implemented to address any potential risks identified.** *Id.*(emphasis added). **The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment."** *Id*. (emphasis added). A good faith risk assessment would have undoubtedly identified the dangers of product contamination in this case. The Defendants have long known that FDA oversight alone is inadequate to ensure the safety of prescription drug products. In fact, the FDA conceded as much in a 2015 report, stating that it "has no formal means for quality surveillance, except through inspections" and admitted that "inspection findings have not been a reliable predictor of the state of quality." *Id.* The FDA further noted that "product recall and defect reporting data demonstrate unacceptably high occurrences of problems attributed to inherent defects in product and process design; these data further indicate failures in the implementation of manufacturing process scaleup as well as routine production." *Id.*

In light of well-documented regulatory enforcement failures, numerous prescription drug recalls, and high-profile cases of adulterated drugs, the Wholesaler Defendants and Retail

Pharmacy Defendants knew very well that the drug products they sold presented serious risks of contamination. Indeed, McKesson "has the unenviable position of being the first Wholesaler to receive a warning letter from the FDA for non-compliance with the DSCSA" specifically with respect to monitoring its inventory for adulterated drugs. PELMC ¶¶ 527-530.

McKesson failed to ensure that the VCDs it purchased from Manufacturer Defendants were properly made in a cGMP-compliant manner, unadulterated, and not misbranded. PELMC ¶ 531. Ordinary diligence by McKesson would have revealed that the VCDs it purchased from Manufacturer Defendants were improperly made, adulterated, or misbranded. For example, McKesson knew or should have known that Manufacturer Defendants utilized different manufacturing and quality practices or controls than those used by the brand-reference drug manufacturer, on account of the public availability of the regulatory submissions on file with the FDA, the information available to McKesson upon request to each Defendant Manufacturer pursuant to the contracts, the information available to McKesson upon request to manufacturers of Diovan or other valsartan, and the price differential between Manufacturer Defendants' VCDs and other properly made, non-adulterated, or non-misbranded valsartan. PELMC ¶ 533.

ii. Plaintiffs' Amendments Plead Cognizable Negligence Claims Against Retail Pharmacy Defendants

Retail Pharmacy Defendants have a duty to use due and proper care in filling prescriptions and selling products to the public. *See, e.g., Arrington v. Walgreen Co*., 664 F. Supp. 2d 1230, 1233 (M.D. Fla. 2009) (under Florida law, pharmacy may be liable for negligence for failure to use due and proper care in filling prescriptions, even if prescription is filled in accordance with physician's instructions). In their amendments, Plaintiffs plead specific allegations as to Retail Pharmacy Defendants' breach of this duty.

For example, Plaintiffs alleged that Retail Pharmacy Defendants are obligated under the

Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs. PELMC ¶ 464. Retail Pharmacy Defendants knew or should have known, based on information provided or available from each manufacturer or Wholesaler Defendant, of the actual or potential adulteration, misbranding, or contamination of VCDs they purchased from manufacturer defendants. *Id.* Retail Pharmacy Defendants expressly or impliedly warranted VCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case. *Id.* Plaintiffs also alleged that Retail Pharmacy Defendants were obligated to ensure that the product they sold was not adulterated or misbranded. PELMC ¶¶ 461-464. Plaintiffs alleged how the Retail Pharmacy Defendants were obligated to comply both with cGMPs as well as Good Distribution Practices. *Id.* ¶¶ 492-503. Plaintiffs also allege that some retail pharmacies do, in fact, test their product to ensure they are not adulterated or misbranded. ¶503.

Moreover, Plaintiffs made detailed allegations as to the actions of specific Retail Pharmacy Defendants. Taking Defendant CVS as an example, Plaintiffs alleged that CVS has represented and warranted that it sells drugs manufactured in accordance with quality standards. For instance, and consistent with representations throughout the relevant time period, CVS claimed that their "purpose" in helping people on a path to better health means ensuring "a safe working environment" for the "suppliers worldwide." PELMC ¶ 556. Plaintiffs also alleged that CVS claimed to adequately monitor the "most critical risks" in the manufacturing supply chain, including health and safety, chemical management, environmental sustainability, recognizing forced labor and corrective action planning. *Id*. ¶ 538. Ordinary diligence by CVS would have revealed that the VCDs it purchased from Manufacturer Defendants were improperly made, contaminated, adulterated, or misbranded. For example, CVS knew or should have known that

Manufacturer Defendants utilized different manufacturing and quality practices or controls than those used by the brand-reference drug manufacturer, on account of the public availability of the regulatory submissions on file with the FDA, the information available to CVS upon request to each Defendant Manufacturer pursuant to their contracts, the information available to CVS upon request to manufacturers of Diovan or other valsartan, and the price differential between Manufacturer Defendants' VCDs and other properly made, non-contaminated, non-adulterated, or non-misbranded valsartan. PELMC ¶ 564. Plaintiffs also alleged that but for CVS's wrongful actions or inactions, at a minimum, at least some of Plaintiffs Semmel, Longwell, Molinaro, Nelson, Kessinger, Glab, Edwards, and other consumers' purchases of valsartan would not have been of improperly made, adulterated, or misbranded VCDs. Plaintiffs made similar allegations as to Defendant Walgreens (PELMC ¶¶ 566-576), Defendant Rite-Aid, (PELMC ¶¶ 577-583) and Defendant Walmart (PELMC ¶¶ 584-596).

5. Plaintiffs' Amendments Adequately Plead Fraud

With respect to fraud, and the other fraud based[25] claims, the Wholesaler Defendants and Retail Pharmacy Defendants argue that "Plaintiffs do not add sufficient detail to their fraud claims to cure the deficiencies identified by the Court." *See* Retail Pharmacy Br. at 22. That is incorrect. In MTD Order No. 4, the Court identified two bases for dismissing without prejudice the fraud-based claims against these downstream defendants, namely 1) lumping Retail Pharmacy Defendants and Wholesaler Defendants together with upstream defendants (e.g., Manufacturers) and 2) failure to identify the "time, place, [and] content of the statement" with the requisite level of particularity under Rule 9(b). MTD Order No. 4 at 19. Plaintiffs have rectified both of these

[25] The phrase "fraud-based claims" as used herein has the same meaning as set forth in the Court's MTD Opinion 4. *See* MTD Opinion 4, at 18 n. 9.

deficiencies, and plausibly assert their fraud-based claims against Wholesaler and Retail Pharmacy Defendants.[26]

[26] Separately, and notably, Defendants overlook that various state consumer protection statutes, at least in certain home states of the named Plaintiffs in the PELMC and PMMMC, require a lesser showing than common law "fraud" and of "reliance." Many require something less stringent such as "deception" or "unfair" acts. Defendants impliedly overstate the pleading requirements in these states by improperly lumping these claims in together with the traditional common law fraud claims. *See, e.g.,* California: *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 160 (E.D. Pa. 2009) (California's UCL provides for causes of action for "unlawful, unfair, or fraudulent behavior;" upholding plaintiffs' CUCL claims under the "unlawful" or "unfair" prongs, noting that "plaintiffs rebut [the reliance] argument by stating that their claims are not limited to fraud, but span all three prongs of the UCL…California courts have emphasized the disjunctive language of this statute."); Colorado: *Hall v. Walter*, 969 P.2d 224 (Colo. 1998) (causation may be established even if the injured party did not rely on the deceptive statements); Florida: *Davis v. Powertel, Inc.*, 776 So.2d 971 (Fla. Dist. Ct. App. 2000) (reliance is not required in either an individual or class action, and that proof that the practice was likely to deceive a reasonable consumer is sufficient); *Fitzpatrick v. Gen. Mills, Inc.*, 635 F.3d 1279, 1283 (11th Cir. 2011) ("a plaintiff need not prove reliance on the allegedly false statement to recover damages under FDUTPA, but rather a plaintiff must simply prove that an objective reasonable person would have been deceived"); Illinois: *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584 (Ill. 1996) (proximate cause, but not reliance, must be shown); Kansas: *Finstad v. Washburn, Univ. of Topeka*, 845 P.2d 685 (Kan. 1993) (courts interpret *Finstad* to say that reliance is not required but is a relevant factor when the court determines whether the consumer is "aggrieved." *See, e.g.*, *McLellan v. Raines*, 140 P.3d 1034 (Kan. App. 2006); *accord Midland Pizza, L.L.C. v. Southwestern Bell Tel. Co.*, 2010 WL 4622191 (D. Kan. Nov. 5, 2010); *Welch v. Centex Home Equity Co.*, 178 P.3d 80 (Kan. Ct. App. 2008); Kentucky: *Telcom Directories, Inc. v. Commonwealth ex rel. Cowan*, 833 S.W.2d 848, 850 (Ky. App. 1991) (not necessary for the state to prove actual deception); *Corder v. Ford Motor Co.*, 869 F. Supp. 2d 835 (W.D. Ky. 2012) (consumer case where the court held that the UDAP statute requires proof of a causal nexus between plaintiff's loss and defendant's allegedly deceitful practices, but reliance is not required); *Brown v. Tax Ease Lien Servicing*, LLC, 2015 WL 7431044, AT *10 (W.D. Ky. Nov. 20, 2015); Maine: *Tungate v. MacLean-Stevens Studios*, 714 A. 2d 792, 797 (Me. 1998) (reliance is not required as "a practice may be deceptive if it 'could reasonably be found to have caused a person to act differently from the way he otherwise would have acted.'"); Maryland: *Nyhart v. PNC Bank*, No. 15-2241, 2016 WL 6996744, at *6 (D. Md. Nov. 30, 2016) (reliance is not necessarily required for claims that do not depend on a violation of the prohibition against false or misleading statements); Massachusetts: *Iannacchino v. Ford Motor Co.*, 888 N.E.2d 879, 886 n.12 (Mass. 2008) (showing of reliance is unnecessary); *Aspinall v. Philip Morris Cos.*, 813 N.E.2d 476, 486 (Mass. 2004); *Heller Fin. v. INA*, 573 N.E.2d 8 (Mass. 1991) (reliance not necessary, but plaintiff must show causal connection between misrepresentation and injury); Minnesota: *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2 (Minn. 2001) (private plaintiffs in damages suit need not plead or prove reliance but must prove causation, which may require direct or circumstantial evidence of reliance); New Mexico: *Lohman v. Daimler- Chrysler Corp.*, 166 P.3d 1091, 1098 (N.M. App. 2007) ("a claimant need not prove reliance upon a

i. Amendments To Plaintiffs' Fraud-Based Claims Against Wholesaler Defendants and Retail Pharmacy Defendants Are Not Futile

As Plaintiffs have previously stated (and as the Court noted in finding that Plaintiffs had plead cognizable fraud claims against the Manufacturers) "[t]he heightened pleading standards of Rule 9(b) have been said to require a plaintiff to identify the 'who, what, where, when, and how' of the fraud." *Transportation Insurance Co. v. Am. Harvest Baking Co., Inc.*, 2015 WL 9049273, at *10 (D.N.J. Dec. 16, 2015) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997)); *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation and quotation marks omitted) (explaining the allegations must contain "the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue"); *Morganroth & Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 414 n.2 (3d Cir. 2003) ("The purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim.").

"As several courts have noted, Rule 9(b)'s 'heightened standard is somewhat relaxed in a case based on a fraudulent omission,' rather than one based on misrepresentation." *Majdipour v.*

defendant's deceptive conduct in" order to sustain a UDAP claim."); *Mulford v. Altria Group, Inc.*, 242 F.R.D. 615 (D.N.M. 2007) (must show causal link but not reliance); *Smoot v. Physicians Life Ins. Co.*, 87 P.3d 545 (N.M. Ct. App. 2003) (proof of causation, but not necessarily reliance, is required); New York: *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 647 N.Y.S.2d 20 (N.Y. 1995) (reliance is not required); *accord Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005) (§349 does not require proof of actual reliance); Pennsylvania: *Gregg v. Ameriprise Fin., Inc.*, 245 A.3d 637, 649 (Pa. 2021) ("[h]ad the General Assembly intended to limit the catch-all provision to cover only common law misrepresentation claims, it would have done so directly by, for example, barring only fraudulent or negligent conduct. By choosing instead to bar "deceptive conduct," the General Assembly signaled its intent to dispense with consideration of the actor's mental state."); Virginia: *Owens v. DRS Automotive Fantomworks, Inc.*, 764 S.E.2d 256 (Va. 2014) (although VCPA claim does not require proof of common law fraud, it does require proof "in misrepresentation cases of the elements of reliance and damages").

Jaguar Land Rover N. Am., LLC, 2013 WL 5574626, at *15 (D.N.J. Oct. 9, 2013) (quoting *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 451 (D.N.J. 2012)); *Feldman v. Mercedes–Benz USA, LLC*, 2012 WL 6596830, at *10 (D.N.J. Dec.18, 2012) ("[P]laintiffs pleading a fraud by omission claim are not required to plead fraud as precisely as they would for a false representation claim.").

In each of the proposed amended master complaints, Plaintiffs provide additional detail as to the specific misrepresentations and omissions made by the Wholesaler Defendants and Retail Pharmacy Defendants, their knowledge of the same, and Plaintiffs' reliance thereon. Specifically, each Wholesaler Defendant and Retail Pharmacy Defendant "misrepresented material facts including, *inter alia*, that their VCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not contaminated, adulterated and/or misbranded." PELMC ¶ 677; PPIMC ¶ 755; PMMMC ¶ 599. These misrepresentations were made at the time of purchase of each VCD by Plaintiffs on "the patient package inserts, medication guides, instructions for use," and on the labeling of each VCD. PELMC ¶ 677; PPIMC ¶ 689, PMMMC ¶ 672. Stated another way, each time Plaintiffs purchased their VCDs, the Wholesaler Defendants and Retail Pharmacy Defendants each represented that the medication being sold to Plaintiffs and other consumers was an approved and lawfully-sold VCD that was not contaminated and did not contain nitrosamines or other impurities. The Pharmacy Defendants also engaged in material omissions by failing to disclose the true nature of the VCDs to Plaintiffs and consumers at the point of sale. *See* PELMC ¶ 678 ("Defendants omitted material facts including, *inter alia*, that their VCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved."); PPIMC ¶ 688; PMMMC ¶ 673.

Despite the foregoing, Wholesaler Defendants and Retail Pharmacy Defendants argue that "Plaintiffs' proposed amendments do not address any of the Court's concerns, still group

defendants together, and fail to provide the level of detail necessary to state a fraud-based claim." Retailer Opp. At 23. But that argument is belied by the well-pleaded facts. Further, that Plaintiffs group these Defendants together in certain instances is not fatal to Plaintiffs' claims because Plaintiffs specifically identify each Pharmacy Defendant and explain their role in the overall system. It is undisputed that each of the retail pharmacies put labels on the VCDs and provided package inserts and medication-related materials to customers who purchased VCDs from them, including Plaintiffs. Plaintiffs likewise specifically identified each Wholesaler Defendant, and articulated their specific role in the chain which ultimately put the VCDs in the hands of the Plaintiffs. Courts have declined to dismiss similar types of allegations on "lumping" grounds. *See In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at *9 (D.N.J. May 8, 2017) (denying motion to dismiss on "lumping" grounds, and explaining that "[w]hile Plaintiffs do use the term 'Defendants' throughout the Complaint, they also make particularized allegations against each Defendant").

Plaintiffs also adequately allege knowledge, which may be "alleged generally" and is not subject to the heightened pleading requirements of Rule 9(b). *See Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 591 (D.N.J. 2016) (explaining "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally, and does not require the plaintiff to plead every material detail of the fraud"). That is precisely what Plaintiffs do here. PELMC ¶¶ 708-712; PPIMC ¶ 394; PMMMC ¶ 471.

In sum, Plaintiffs adequately plead their fraud-based claims in the PELMC, PPIMC, and PMMMC, and therefore their proposed amendments are not futile.

6. Plaintiffs' Amendments to Products Liability Act Claims Are Not Futile

The Manufacturer and Wholesaler Defendants did not raise Product Liability Act ("PLA")

issues in their motions. However, the Retail Pharmacy Defendants take issue with claims brought under various states' PLAs in the PPIMC. In their motion to dismiss the first PIMC, Defendants argued: "All state law claims (except for breach of express warranty) brought by New Jersey [Plaintiffs] … are subsumed by the NJPLA and should be dismissed. The PIMC's claims are subsumed because they emanate from physical harm." ECF 520-3, p. 33.[27] Defendants made the same argument for product liability acts of Connecticut, Indiana, Kansas, Louisiana, Mississippi, North Carolina, Ohio, Tennessee, and Washington. ECF 520-3, p. 33; 520-5, pp. 16-19. The Court granted this motion for New Jersey (except for breach of express warranty), Connecticut, Indiana[28] (except for violation of state consumer protection statutes, breach of express warranty, and breach of implied warranty), Kansas (except the claim for violation of state consumer protection statutes), Louisiana, Mississippi (except the claims for fraud and violation of state consumer protection statutes), North Carolina,[29] Ohio (except for fraud), Tennessee (except the claim for violation of state consumer protection statutes), and Washington[30] (except the claims for violation of state consumer protection statutes and fraud). *See* ECF 838, pp. 36-38. Thus, the Defendants now contradict their position taken during the last round of briefing.

As to the Retail Pharmacy Defendants, Plaintiffs seek leave to amend as to their claims under the Kansas Product Liability Act, New Jersey Product Liability Act, North Carolina Product Liability Act, Ohio Product Liability Act, and Washington Product Liability Act. PPIMC ¶¶ 765–

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[27] The Pharmacy Defendants specifically incorporated these subsumption arguments in their motion to dismiss brief and its Exhibit A. *See* ECF 523-1, p.4; ECF 523-2.

[28] The Pharmacy Defendants do not challenge Plaintiffs' amendments under Indiana's Product Liability Act at this time. *See* ECF 1280, p. 39 n.14.

[29] The Pharmacy Defendants do not challenge Plaintiffs' amendments under North Carolina's Product Liability Act at this time. (ECF 1280, p. 39 n.14).

[30] Plaintiffs agree with the Pharmacy Defendants that Washington recognizes "express warranty-, negligence-, [and] fraud-based claims" but not strict liability ones under the Washington Product Liability Act. *See* ECF 1280, p. 41; *see also* R.C.W. 7.72.010; R.C.W. 7.72.040.

805.[31]

The Retail Pharmacy Defendants do not oppose Plaintiffs' Motion to Amend the PIMC with respect to the claims asserted under the Indiana Product Liability Act or the North Carolina Product Liability Act; therefore, leave to amend should be granted with respect to those claims. *See* Retail Pharmacy Br. at 39 n.14.

However, as to the remaining states, the Retail Pharmacy Defendants now argue that these product liability acts do not recognize claims against pharmacies. Retail Pharmacy Br. at pp. 40-44. This argument clearly contradicts the Pharmacy Defendants' prior contention that claims plead pursuant to these acts were the only claims available to Plaintiffs in these states. If these acts do not apply to the Pharmacy defendants, then Plaintiffs clearly have recourse as to the common law claims that the Pharmacy Defendants previously moved the Court to dismiss as subsumed.

i. Retail Pharmacy Defendants are subject to the Kansas Product Liability Act.

The Retailer Defendants allege they are exempt from PLA claims under Kansas law because they argue Plaintiffs brought claims against pharmacists. This demonstrates a fundamental misunderstanding of Plaintiffs' claims. Plaintiffs brought claims against the corporate entities (not individual pharmacists), which owed duties to Plaintiffs to sell safe, unadulterated, un-misbranded drugs. Nowhere in Plaintiffs' PPIMC do they seek to hold individual pharmacists liable.

Retail Pharmacy Defendants are general corporations and limited liability companies subject to the Kansas Product Liability Act ("KPLA") as product sellers. *See* Kan. Stat. § 60-3302(a); APIMC ¶¶ 57, 65, 69, 73, 77, 80, 82, 84, and 86. While the KPLA does exempt "health care providers," (defined to include actual pharmacists under Kansas Statutes Annotated

[31] As to the other Defendant groups, Plaintiffs seek leave to amend as to a broad set of states, set forth in the PPIMC.

40-3401(f)), it does not exempt pharmacies and the Retail Pharmacy Defendants do not (and cannot) make this argument. Because the Retail Pharmacy Defendants are large corporations, they are "product sellers" under the KPLA. K.S.A. 60-3302(a). Again, the claims here are not medical negligence claims that the statutes intended to except.

Indeed, the Kansas Product Liability Act embraces an "expansive" definition of "product seller" that does not even require "transfer of title" for an entity to qualify as a product seller. *Cooper v. Zimmer Holdings, Inc.*, 320 F. Supp. 2d 1154, 1159 (D. Kan. 1997). In defining the term "product seller" more "broadly" under the Kansas Product Liability Act than it had under other statutes, the Kansas Legislature defined it to include entities including distributors and retailers. *Id.* at 1158. In *Cooper*, the Court concluded that the defendant was a "product seller" because it was a distributor and therefore one of the entity types listed in the statute. *Id.* at 1159. Here, the Retail Pharmacy Defendants constitute "product sellers" under the broad definition that term carries within the meaning of the Kansas Product Liability Act. The Retail Pharmacy Defendants engaged in the business of selling pharmaceutical products to consumers, including Plaintiffs, for their consumption and use, often at retail store locations. *See* Kan. Stat. Ann. § 60-3302 (defining "product seller" as any "entity that is engaged in the business of selling products"). As in *Cooper*, the determination of whether the Retail Pharmacy Defendants are product sellers is a simple one because they are precisely the type of entity the Kansas Legislature identified as a product seller—regardless of the professionals they happen to employ. 320 F. Supp. 2d at 1159 (focusing inquiry on defendant's status as distributor).

As such, amendment of the PPIMC is not futile with respect to claims asserted under the Kansas Product Liability Act because the Act applies to the Retail Pharmacy Defendants as "product sellers" and leave to amend should be granted.

ii. Retail Pharmacy Defendants are subject to liability under the Washington Product Liability Act.

Just as was the case with the Kansas PLA, claims under which the Retail Pharmacy Defendants once again seek to avoid liability include those under the Washington PLA, with the incorrect assumption that Plaintiffs are seeking to hold individual pharmacists liable. The Retail Pharmacy Defendants argue that amendment of the PPIMC with respect to claims asserted under the Washington Product Liability Act is futile because the Retail Pharmacy Defendants are not "product sellers" under the Act and, instead, are pharmacists that fall within the pharmacist exclusion. Retail Pharmacy Br. at 41. However, the pharmacist exclusion is specific to "licensed pharmacist[s]."

Liability can be imposed upon the Retail Pharmacy Defendants pursuant to the Washington Product Liability Act as "product sellers," because the Retail Pharmacy Defendants are engaged in the business of selling products and, as corporate entities that cannot be licensed as pharmacists, are not excluded from the Act's coverage. The Washington Product Liability Act establishes grounds for imposing liability on product sellers other than manufacturers. Wash. Rev. Code § 7.72.050. Within the meaning of the Washington Product Liability Act, the term "product seller" means "any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption" and includes retailers of the relevant product. Wash. Rev. Code § 7.72.010(1). However, the term "product seller" does not include a "licensed pharmacist who dispenses a prescription product manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed prescribing practitioner if the claim is based upon strict liability in tort or the implied warranty provisions" under the Uniform Commercial Code and recordkeeping and administrative requirements. Wash. Rev. Code § 7.72.010(1)(e).

The Retail Pharmacy Defendants argue that amendment of the PPIMC with respect to claims asserted under the Washington Product Liability Act is futile because the Retail Pharmacy Defendants are not "product sellers" under the Act and, instead, are pharmacists that fall within the pharmacist exclusion. Retail Pharmacy Br. at 41. However, the pharmacist exclusion is specific to "licensed pharmacist[s]."[32]

The Retail Pharmacy Defendants, as corporate entities, simply cannot satisfy those requirements and are not licensed as pharmacists in the state of Washington. The Washington Product Liability Act does not exclude those who "employ" licensed pharmacists from the definition of "product seller." *See* Wash. Rev. Code. § 7.72.010(1)(e). Only licensed pharmacists who actually dispense prescriptions themselves are excluded from the definition of "product seller." *Id.* Plaintiffs have not brought malpractice claims against their pharmacies. Instead, the PIMC seeks to hold the corporations, who had legal obligations to ensure they sold products that complied with cGMPs and their own quality agreements, accountable for their failures in both arenas. For these reasons, Plaintiffs' proposed amendments are not futile.

iii. Retail Pharmacy Defendants Are Subject to Liability Under the Ohio Product Liability Act

The Ohio Product Liability Act applies to "supplier[s]," which include any "person that, in the course of a business… sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce." Oh. Rev. Code § 2307.71(A)(15)(a)(i).

[32] To obtain a pharmacy license in Washington, a person must be at least eighteen years of age, satisfy character and professional requirements, hold a baccalaureate or doctor of pharmacy degree from an accredited institution, complete internship requirements, and pass an examination. Wash. Rev. Code. § 18.64.080.

Supplier liability in Ohio is not limited to sales in the traditional sense but includes any person who places a product into the stream of commerce that exercises control over the product. *Stiner v. Amazon.com, Inc.*, 164 N.E3d 384, 399 (Ohio 2020); *Saylor v. Providence Hosp.*, 680 N.E.2d 193, 195 (Ohio Ct. App. 1996). Supplier liability in Ohio is not limited to sales in the traditional sense, but includes any person who places a product in the stream of commerce as long as they exercise control over the product. *Stiner v. Amazon.com, Inc.*, 164 N.E.3d 384, 399 (Ohio 2020); *Saylor v. Providence Hosp.*, 680 N.E.2d 193, 195 (Ohio Ct. App. 1996) (explaining that Ohio Rev. Code § 2307.71 codifies an earlier decision of the Ohio Supreme Court that "declined to limit supplier liability to an actual sale in the traditional sense."). In *Stiner*, the Ohio Supreme Court applied this analysis to determine the supplier liability of Amazon and a third-party vendor that sold products on Amazon.com. 164 N.E.2d at 399. The Court explained that Amazon was not a supplier because it had "no relationship with the manufacturer or entities in the seller's distribution channel," and "never physically touched the product." *Id.* By contrast, the third-party vendor was a supplier because it took responsibility for the product, from sourcing it from a manufacturer until it reached the end user. *Id.* The Retail Pharmacy Defendants are suppliers under Ohio Rev. Code § 2307.71 because they placed the products in the stream of commerce and exercised control over the product. *Id.*; *Saylor*, 680 N.E.2d at 195. Unlike Amazon, the Retail Pharmacy Defendants had relationships with others in the distribution channel because they contracted directly with both manufacturers and wholesalers for the sale of the products; the Retail Pharmacy Defendants also physically controlled the product when they dispensed it directly to consumers in exchange for payment. PPIMC ¶¶ 54–55. Like the third-party vendor, the Retail Pharmacy Defendants took responsibility for the product, sourcing it from the manufacturer through their supply arrangements until the time that it reached the end users. *Id.* The Retail

Pharmacy Defendants in this case have placed the product in the stream of commerce and exerted the requisite control over the product as required to establish supplier liability under Ohio law. *See Stiner*, 164 N.E.3d at 399.

The Retail Pharmacy Defendants argue that amendment of the PPIMC with respect to claims asserted under the Ohio Product Liability Act is futile because they are "professional service providers" rather than "suppliers." Retail Pharmacy Br. at 43-44. However, the Retail Pharmacy Defendants did not exercise the professional judgment contemplated under the PLA that underpins this part of the law. The Retail Pharmacy Defendants received a prescription and filled it as written. The Retail Pharmacy Defendants have not included any facts in their Opposition to demonstrate that there was any judgment in their decision to sell VCDs to Plaintiffs, nor do they allege that such judgment was the "essence" of the transaction and not merely incidental as required by Oh. Rev. Code § 2307.71(A)(15)(b)(iii). To the extent the pharmacists employed by the Retail Pharmacy Defendants happened to possess additional judgment or skill, it was only incidental to the transaction. Given the broad definition of "supplier," Ohio courts have shown reluctance to find that entities providing medical products in addition to other medical services were not suppliers before the close of discovery. *See Saylor*, 680 N.E.3d. at 195 (holding that trial court "erred in entertaining a Civ. R. 12(B)(6) motion at all" on the issue of supplier liability and remanding for further proceedings where the plaintiffs asserted that a hospital that placed a plate and screws into a plaintiff's back during surgery was a "supplier"). Thus, even if the Retail Pharmacy Defendants provided incidental services in addition to supplying products for sale, they do not render Plaintiffs' claims under the Ohio Product Liability Act futile and arguments regarding such services are not appropriate for consideration at this stage of proceedings.

iv. Retail Pharmacy Defendants Are Subject to Liability Under the New Jersey Product Liability Act

The New Jersey Product Liability Act imposes liability on both the manufacturer or seller of a product. N.J. Stat. Ann. 2A-58C-2. A "product seller" under the New Jersey Product Liability Act is "any person who, in the course of business conducted for that purpose: sells; distributes; leases; installs; prepares; . . . blends; packages; labels; markets; repairs; maintains or otherwise is involved in placing a product in the line of commerce." N.J. Stat. Ann. § 2A:58C-8(1)(1). However, the term "product seller" does not include a "provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services." N.J. Stat. Ann. § 28-58C-8(1)(2). That exception is not applicable here.

The Retail Pharmacy Defendants once again contend that they are not "product sellers" because they are "service providers." Retail Pharmacy Br. at 44. However, Plaintiffs' case against the Retail Pharmacy Defendants focuses on their sale of contaminated VCDs – these are not medical negligence claims which are clearly the type of claims excepted from the PLA. The same holds true across the similar statutes cited by the Defendants.

It is well-established in New Jersey that "a business owner or service provider is not strictly liable in tort for defects in products used only incidentally in its business . . . a basic reason for imposing strict liability was to hold accountable those who place a product into the stream of trade and promote its purchase by the public." *Becker v. Tessitore*, 812 A.2d 369, 379 (N.J. Super. App. Div. 2002). "Releasing a product 'into the stream of commerce' means 'that the product itself is presently and physically sold, leased or its possession exchanged.'" *Id.* at 380 (quoting *Woods v. Luertzing Corp.*, 400 A.2d 562 (N.J. Law Div. 1979)). For example, where a dentist had used a defective hypodermic needle, he "was not in the business of supplying the product to the patient

but rather was in the business of providing dental service" because he "had not placed the needle into the stream of commerce nor had he promoted its purchase." *Id.* at 379 (discussing *Magrine v. Krasnica*, 227 A.2d 539 (N.J. Cty. Ct. 1967)). Likewise, in *Becker*, the court held that in the case of a tire bailment, because there was no exchange in ownership, the defendant had not released the product into the stream of commerce and was therefore not a product seller but rather a service provider. *Id.* at 380, 382.

Here, however, the Retail Pharmacy Defendants are "product sellers" rather than "service providers" because they placed pharmaceutical products "in the line of commerce." N.J. Stat. Ann. 2A-5AC-8(1). That is, the Retail Pharmacy Defendants "promote[d] its purchase by the public" when they "physically sold" the product by dispensing the product to customers for a price. *See Becker*, 812 A.2d at 379. As interpreted by New Jersey courts, the distinction between "product seller" and "service provider" comes down to an exchange in ownership. Such an exchange in ownership is characteristic of the relationship between Plaintiffs and the Retail Pharmacy Defendants, as the primary reason for Plaintiffs' interactions with the Retail Pharmacy Defendants was to pay for and obtain ownership of the VCDs.

Plaintiffs primarily went to Pharmacy Defendants to obtain VCDs, not to receive specific services provided by the Retail Pharmacy Defendants. To the extent they provided any "pharmacy services," those services were entirely incidental to the sale of the drug. Moreover, if the sale of the VCDs were truly "incidental" to Plaintiffs' claims, Plaintiffs would be entitled to sue the Pharmacy Defendants as service providers under the common law. *See* Dreier et al, *Current N.J. Prods. Liab. & Toxic Tort L.* § 12:1-5(c) (2021) (stating the blackletter law that "providers of services have always been liable for negligence in performance"); *see also Sun Chem. Corp. v. Fike Corp.*, 243 N.J. 319, 338 (2020) (holding that the test for subsumption is "whether the claim

is based upon a product's manufacturing, warning, or design defect and therefore covered by the PLA"). The Court should allow Plaintiffs' amendments to the PIMC articulate one of these theories, as the Retailers are essentially requesting blanket immunity no matter how the claims are presented, which is not the law.

v. Retail Pharmacy Defendants Are Subject to Liability Under the Mississippi Products Liability Act

In the case of Mississippi, the Retail Pharmacy Defendants rely entirely on *In re Rezulin Products Liability Litigation*, 133 F. Supp. 2d 272, 288-90 (S.D.N.Y. 2001). Retail Pharmacy Br. at 43. That case did not involve manufacturing defect claims and gross violations of cGMPs, such as this case. As a result, the *Rezulin* court focused on how holding the pharmacies liable would interfere with Mississippi's learned intermediary doctrine and the physicians' relationships with patients. 133 F. Supp. 2d at 288-90. Here, the Pharmacy Defendants were in a far better position to know of the manufacturing defects at issue. At the Court knows, not all valsartan was contaminated, and a physician would have no way to know which manufacturer's valsartan the Pharmacy Defendants would dispense. Thus, holding the Pharmacy Defendants liable for selling such defective drugs would not interfere with the learned intermediary doctrine or Plaintiffs' relationships with their physicians. The Court should consequently grant Plaintiffs' motion to amend to include these claims.

vi. Retail Pharmacy Defendants Are Subject to Liability Under the Tennessee Products Liability Act

The Pharmacy Defendants rely on a similarly inapplicable case regarding Tennessee law: *In re New England Compounding Pharmacy, Inc.*, MDL No. 13-02419, 2016 WL 11045600, at *2 (D. Mass. Feb. 29, 2016).[33] There, the court noted that "[u]nder the plain meaning of their

[33] The Pharmacy Defendants also rely on *Heaton v. Mathes*, No. E2019-00493-COA-R9-CV, 2020

coverage provisions, both the [Tennessee Health Care Liability Act (THCLA)] and the [Tennessee Product Liability Act (TPLA)] could apply here, as the plaintiffs' allegations concern both a defective product and the provision of health care services." *Id.* at *2. Here, Plaintiffs have focused their allegations on the Pharmacy Defendants' sale of the contaminated VCDs, not their provision of health care services. Thus, the TPLA applies to Plaintiffs' claims, not the THCLA.

vii. Plaintiffs Are Entitled to Plead Alternative Claims if PLA Claims Cannot Proceed Forward as to Retail Pharmacy Defendants

To the extent the Retail Pharmacy Defendants are poised to now argue that the PLA does not or cannot apply to them, then in the event that were correct (which it is not), then Plaintiffs clearly have recourse to the common law claims that the Pharmacy Defendants previously moved the Court to dismiss as subsumed. This is particularly true for Connecticut, which recognizes that there must be a viable avenue of recovery. *Altieri v. CVS Pharmacy, Inc.*, 2002 WL 31898323, at *4 (Conn. Super. Ct. Dec. 13, 2002) (dismissing a Connecticut Products Liability Act claim because "filling a prescription is a service and not the sale of a product as required by Connecticut products liability law" but not dismissing the plaintiff's negligence claims).

Given the foregoing, to the extent the Court finds that claims under the PLA do not apply to Retail Pharmacy Defendants, Plaintiffs should be permitted to pursue alternate common law claims.

7. Plaintiffs Have Properly Plead Medical Monitoring – As a Claim or Remedy – Against Defendants

WL 1652571, at *7-8 (Tenn. Ct. App. Apr. 3, 2020). Retail Pharmacy Br. at 42. However, that case concerned "whether the seller shield defense contained within the TPLA may be applied to provide immunity for a defendant sued under the THCLA," not whether a plaintiff could plead a TPLA claim against a pharmacy without invoking professional negligence. *Heaton v. Mathes*, 2020 WL 1652571, at *7 (Tenn. App. April 3, 2020).

Defendants oppose Plaintiffs' amendment arguing that Medical Monitoring, either plead as a claim, or a remedy, cannot proceed forward under the law of a variety of states. However, the Medical Monitoring Plaintiffs' claims should be permitted to proceed forward to allow for full factual development. Moreover, the law of these challenged states does not permit dismissal at this juncture.

i. Subsumption Does Not Materially Impact Plaintiffs' Medical Monitoring Claims

Defendants concede that MTD Order No. 5's subsumption ruling *only* implicated[34] Louisiana state-law claims in the ELMC, and eight claims under eight states' laws in the MMMC. *See* Manuf. Br. at 24-25.

As to the point of whether the claims of these 9 states are now subsumed, Defendants' argument inappropriately elevates form over function. As a matter of state law, it is not necessary to plead explicitly 'magic words' to assert various state-law theories (e.g., breach of warranty, etc.) under a state's Product Liability Act. *See, e.g.*, *Lewis v. GE Healthcare, Inc.*, No. 5:19-cv-00490, 2020 WL 1490719, at *4 (W.D. La. Mar. 25, 2020).[35]

Regardless, it is undisputed that Plaintiffs expressly pleaded the appropriate state law

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[34] None of the Defendants re-raise their subsumption arguments as to the PPIMC. Thus, Defendants concede that Plaintiffs have addressed the Court's subsumption concerns in MTD Order No. 5.

[35] "GEHC contends that these claims fail because Lewis did not explicitly assert a claim under the LPLA. It is manifest, however, that a complaint need not 'correctly specify the legal theory giving rise to the claim for relief.' Further, '[c]ourts must focus on the substance of the relief sought and the allegations pleaded, not on the label used." Because failure to warn, breach of express warranty, and unreasonably dangerous design are cognizable under the LPLA [Louisiana Product Liability Act], the Court will proceed to determine whether Lewis alleged sufficient facts to support these claims." *Id.* at *4; *see also King v. Bayer Pharm. Corp.*, No. CIV.A. 09-0465, 2009 WL 2135223, at *5 (W.D. La. July 13, 2009) ("Clearly, Plaintiffs' complaint contains the requisite factual allegations to state a claim under the LPLA. Moreover, the factual allegations support claims under the LPLA, even though Plaintiffs' complaint used titles for their claims that fell outside the LPLA.").

Product Liability Acts in the PPIMC, which Defendants concede was sufficient. If Defendants insist on same form-over-function, then Plaintiffs have addressed this ministerial matter by adding the same simple language in the PPIMC to the ELMC and PMMMC. *See* Exs. A-1, A-2, B-1, B-2, C-1, C-2.[36]As these identical amendments were sufficient for the PPIMC, Defendants cannot dispute that they are equally sufficient for the PELMC and PMMMC.

Moreover, Defendants clearly are on notice of these claims under products liability statutes, as they are plead in the PPIMC. PPIMC ¶¶ 765-805. The submission of three separate pleadings in this proceeding is an effort to achieve administrative efficiency, and not because the claims are mutually exclusive. *See* PMMMC at p. 1, n. 1 ("Medical Monitoring Class Plaintiffs do not waive any claims that are not raised herein, or that are asserted in another master complaint.").

With respect to Defendants' argument that these subsumed claims should now be dismissed for a failure to plead an injury, Defendants are incorrect on both the allegations, and the law. As a threshold manner, the Medical Monitoring Plaintiffs have, indeed, alleged a present injury. In their PMMC, Medical Monitoring Plaintiffs clearly allege, on behalf of themselves and absent class members, a present physical injury in the form of a cellular and/or genetic injury, and the sort of specific future injury that underlies the entire theory of medical monitoring. PMMMC ¶¶ 386, 397-412, 344, 380, 582, 590, 618.

Defendants' argument as to the law of these states whose common law claims are subsumed is also misleading and purposefully misconstrues the law of these states to arrive at the erroneous conclusion that medical monitoring claims must be dismissed. Using Louisiana as an example of Defendants' flawed logic, Louisiana's product liability statute does exclude medical

[36] This includes language for Plaintiff O'Neill in the PMMMC for Kansas, which Manufacturer Defendants address elsewhere in their brief. *See* Manuf. Br. at 10.

monitoring unless "directly related to a manifest physical or mental injury or disease." La. Civ. Code. art. 2315(B). In *Guillot*, the plaintiffs did not provide any allegation that the present physical injury actually required medical monitoring, and the case was dismissed for lack of standing. *Guillot v. Aventis Pasteur, Inc.*, No. CIV. A 02-3373, 2013 WL 4508003, at *7 (E.D. La. Aug. 22, 2013). More recent cases have found that a cellular injury, presently undiagnosed, can meet the definition of "manifest physical or mental injury" under the statute. *See Spring v. Shell Oil Co.*, 2018 WL 1914293, at *6-7 (M.D. La. Apr. 23, 2018) (finding that allegations of a "lump in throat" due to radiation exposure were sufficient to constitute present physical injury).

Defendants' arguments as to New Jersey and their reliance on *Sinclair* is similarly misplaced and misleading. Plaintiffs are seeking medical monitoring both as an independent cause of action, and also as a remedy. In *Sinclair* the New Jersey Supreme Court only barred medical monitoring claims where a physical injury is not alleged. *See Indian Brand Farms v. Novartis Crop Protection, Inc.*, 890 F. Supp. 2d 534, 541 n. 6 (D.N.J. 2012) (citing *Sinclair v. Merck & Co.*, 948 A.2d 587, 588-89 (N.J. 2008)). Defendants' arguments as to the other states are equally flawed for similar logical gymnastics:

- ***Connecticut***: Manufacturer Defendants' citation to *Bowerman* is misplaced. In that case, unlike here, there was no allegation of a present physical injury. *Bowerman v. United Illuminating*, 1998 WL 910271, at *10 (Conn. Super. Ct. Dec. 15, 1998). Further, the Connecticut Supreme Court recently found that medical monitoring is indeed available under Connecticut law if expert testimony establishes the existence of a subcellular injury. *Dougan v. Sikorsky Aircraft Corp.*, 2020 WL 5521391, at *7-8 (Conn. Sep. 14, 2020) *See* PMMMC at p. 1, ¶ 386; *see, e.g.*, *id.* at p. 10, ¶ 399 ("Plaintiff suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.").

- ***Indiana***: Despite Defendants' implication, Indiana's product liability statute is actually silent on the nature of physical injury required, and thus does not preclude cellular injury. Ind. Code. § 34-20-1-1.

- ***Kansas***. The statute does not exclude cellular injury from the definition, and Defendants provide no citation that a cellular injury would not be recognized. *See* Kan Stat. Ann. § 60-3302.

- ***Tennessee***. Defendants point out that Tennessee's product liability statute requires a physical injury. Plaintiffs' allegations fall within the scope of the statute, which requires a "personal injury." *See* Tenn. Code. Ann. § 29-28-102(6) (2008).

- ***Washington***. While Washington's product liability statute requires a physical injury, the Plaintiffs in *Duncan* did not allege a physical injury, and thus medical monitoring was not recognized as an independent tort. *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 609 (W.D. Wash. 2001).

The Medical Monitoring Plaintiffs recognize that there will be a full factual record developed with the assistance of expert testimony on the question of their present injury. But for the purposes of the Court's inquiry at this stage, taking all allegations as true and in the light most favorable to the Medical Monitoring Plaintiffs, these claims must be permitted to proceed.

ii. Plaintiffs Have Properly Plead Medical Monitoring Against the Retail Pharmacy Defendants

The Retail Pharmacy Defendants make a secondary argument as to the futility of amendments related to Medical Monitoring under the laws of California, Florida, Kansas, Maryland, New Jersey and Texas.[37] However, these arguments miss the mark.

1. Florida

While Defendants concede that Florida law recognizes medical monitoring as a cause of action, they argue that the PMMMC does not make the required showing of negligence for such a claim to proceed forward. Retail Pharmacy Br. at 37*; see also Petito v. A.H. Robins Co.,* 750 So. 2d 103, 105, 107 (Fla. Dist. Ct. App. 1999). However, Florida's negligence requirement for a medical monitoring claim is easily met here. The proposed amendments include clear allegations that the Pharmacy Defendants were negligent, and the complaint presents a viable negligence claim. As the proposed amendments illustrate, high profile drug contamination events, as well as

[37] The Retail Pharmacy Defendants do not contest Plaintiffs' ability to plead a medical monitoring claim under Illinois Law so Plaintiffs do not address it here. *See* Retail Pharmacy Br. at 38.

statements from the United States Government concerning the limitations of FDA oversight, put the Defendants on notice of the significant dangers posed by drugs entering the United States supply chain. *See* PMMMC ¶¶ 154-59. Plaintiffs allege that even where the drugs were correctly manufactured, the temporal and logistical realities of the drug supply chain necessitate testing by retail pharmacies. *Id.* at 159. Despite this, Pharmacy and Wholesale Defendants failed to exercise reasonable care in assessing the quality and safety of the valsartan containing drugs.

2. Kansas

Rather than discussing the substance of medical monitoring law in Kansas, the Pharmacy Defendants note that Plaintiffs did not plead a cause of action under the Kansas PLA. *See* Retail Pharmacy Br. at 38. As stated above, however, Plaintiffs' inadvertent failure to plead the Kansas PLA does not render the medical monitoring complaint futile. Plaintiffs have further made the appropriate corrections to the PMMMC as attached. *See* Exs. C-1, C-2.

3. California

As conceded by Defendants, medical monitoring is recognized as a remedy in California. *See* Retail Pharmacy Br. at 37; *see also Lockheed Martin Corp. v. Super. Ct.*, 29 Cal. 4th 1096, 1107 (Cal. 2003) (noting that the California Supreme Court has recognized medical monitoring as a remedy); *Xavier v. Philip Morris USA Inc.*, No. C 10-02067, 2010 WL 3956860, at *4 (N.D. Cal. Oct. 8, 2010) ("In California, medical monitoring is a remedy which must rely upon underlying claims."). The California Plaintiffs have a strong case here for medical monitoring as a remedy to their claims. Indeed, "[a] claim for medical monitoring can succeed in California where the same claim would fail categorically elsewhere." *Id.* Notably, the California Supreme Court eliminated the present physical injury requirement for medical monitoring. *Id.* Furthermore, California plaintiffs are not required to "prove emotional distress from fear of cancer or a threat of

a future injury that is more likely than not to occur." *Id.*

4. Maryland

Similarly, Maryland Plaintiffs continue to pursue medical monitoring as a *remedy* for their claims. As conceded by Defendants, *see* Doc. 1280 at 37-38, medical monitoring is recognized as a remedy in Maryland. *Exxon Mobil Corp. v. Albright*, 71 A.3d 30, 76 (Md. 2013) (agreeing with "sister jurisdictions that allow recovery for medical monitoring ... as a remedy").

5. Texas

Finally, Texas Plaintiffs continue to pursue medical monitoring as a remedy in Texas. MTD Order No. 5. at 33 clearly states that this ruling does not affect or prejudice plaintiffs' seeking recovery for medical monitoring in concert with any other claim[.]"

Accordingly, Plaintiffs pursue medical monitoring as a cause of action (and remedy) in Florida, Illinois, and Kansas while simultaneously pursuing the remedy of medical monitoring in California, Maryland, [New Jersey,[38]] and Texas.

8. Plaintiffs' Amendments Adequately Plead Strict Liability

Plaintiffs seek leave to amend the PIMC with respect to their strict liability failure to warn and design defect claims. In the Amended PPIMC, Plaintiffs asserted strict liability failure to warn and design defect claims arising under the laws of Connecticut, Mississippi, Missouri, South Carolina, and Texas as to the Retail Pharmacy Defendants. PPIMC ¶¶ 597–619.

The Retail Pharmacy Defendants argue that Plaintiffs strict liability failure to warn and design defect claims arising under the laws of Iowa and North Dakota are futile and cannot be maintained under the laws of those states; however, the Retail Pharmacy Defendants' argument is

[38] As noted above, the New Jersey Supreme Court only barred medical monitoring when the plaintiff fails to allege a physical injury, an oversight Plaintiffs have not made here. Consequently, Defendants are unable to present a persuasive futility argument.

based on a legal theory—innocent seller statutes —that the court has previously rejected as being dispositive at this stage of the litigation. Retail Pharmacy Br. at 47–48; MTD Order No. 4, at 27–28.

i. Plaintiffs Have Claims Under North Dakota Law

In ruling on the Retail Pharmacy Defendants' prior Motion to Dismiss, the Court did not rule on the viability of Plaintiffs' strict liability failure to warn and design defect claims arising under the laws of North Dakota. However, in arguing that Plaintiffs' North Dakota strict liability claims are futile, the Retail Pharmacy Defendants merely recycle the same innocent seller arguments the Court has repeatedly stated should not be considered until the summary judgment stage of proceedings. Retail Pharmacy Br. at 47 n.20; MTD Order No. 5, at 34.

The Retail Pharmacy Defendants rely on *Rostvet v. Lock City Transp. Co., Inc.*, Civ. No. 2:11-cv-21, 2013 WL 11941563, at *6 (D.N.D., Nov. 7, 2013), where the court dismissed a product liability claim against a nonmanufacturing seller pursuant to North Dakota's innocent seller statute, N.D. Cent. Code § 28-01.3-04(2). Retail Pharmacy Br. at 47. However, this Court previously denied the Retail Pharmacy Defendants' Motion to Dismiss strict liability claims based on innocent seller statutes, noting that such statutes include "numerous exceptions or prerequisites for immunity" and that courts "overwhelmingly" address the merits of that defense at the summary judgment stage. MTD Order No. 4. at 27–28. In ruling on the Retail Pharmacy Defendants' Motion to Dismiss strict liability claims, the court specifically did not consider arguments regarding innocent seller statutes. MTD Order No. 5, at 34. Pursuant to the court's guidance in denying the Retail Pharmacy Defendants' Motion to Dismiss, innocent seller statutes do not preclude strict liability failure to warn or design defect product claims and the proper stage of proceedings to challenge such claims would be summary judgment. Defendants attempt to relitigate the issue of whether innocent seller statutes preclude strict liability claims—which the

court has already determined is an issue for summary judgment--by repackaging its Motion to Dismiss arguments as an opposition to Plaintiffs' proposed amended complaints. However, consistent with the Court's prior decisions, the existence of an innocent seller statute does not bar strict liability claims from proceeding. Plaintiffs' North Dakota strict liability failure to warn and design defect claims are not futile and leave to amend the PIMC with respect to those claims should be granted.

ii. Plaintiffs Have Claims Under Iowa Law

Under Iowa law, "the rule of strict liability in tort applies to a retailer as well as a manufacturer of a defective product." *Kleve v. Gen. Motors Corp.*, 210 N.W.2d 568, 571 (Iowa 1973). However, some Iowa courts have analyzed the availability of strict product liability claims under Iowa's innocent seller statute, Iowa Code Ann. § 613.18. *See Merfeld v. Dometic Corp.*, 306 F. Supp. 3d 1070, 1079–80, 1082 (N.D. Ia 2018) (explaining that Ia. Code § 613.18 expressly immunizes one who sells products from various claims under specified circumstances and conditions). The court previously denied the Retail Pharmacy Defendants' Motion to Dismiss based on innocent seller statutes, noting that there are "numerous exceptions or prerequisites for immunity" under such statutes which courts normally address at the summary judgment stage. MTD Order No. 4, at 27. Indeed, in *Kleve*, the Iowa Supreme Court reversed and remanded an order granting a motion for a directed verdict that was based on Iowa's innocent seller statute, finding that there was a strict liability issue for the jury. 210 N.W.2d at 575. Likewise, the court granted in part and denied in part the Retail Pharmacy Defendants' Motion to Dismiss Plaintiffs' strict liability claims, granting the motion only as to "those states that unequivocally prohibit such claims." MTD Order No. 5, at 5. The Court explained that it carefully reviewed the cases cited by the Retail Pharmacy Defendants looking for, among other things, "arguments based

on innocent seller statutes." MTD Op. 5, at 34, ECF No. 83. The Court ultimately both granted and denied without prejudice the Retail Pharmacy Defendants' Motion to Dismiss Plaintiffs' strict liability claims arising under the laws of Iowa. MTD Order No. 5, at 35.

Consistent with the Court's prior analysis of the interplay between strict liability claims against pharmacies and innocent seller statutes, Plaintiffs' strict liability claims arising under Iowa law are not futile because the only case law barring such claims from proceeding is based on an innocent seller statute and does not even specifically reference the applicability of strict liability claims against pharmacies. *Merfeld*, 306 F. Supp. at 1079–80. Leave to amend should therefore be granted.

9. Derivative Claims

Wholesaler Defendants seek to dismiss the PPIMC's derivative claims. The PPIMC's wrongful death, survival, and loss of consortium claims are derivative of the other claims. There is no basis to dismiss these claims at this juncture. *See., e.g.*, *Giardina v. Bennett*, 545 A.2d 139, 145 (N.J. 1988) (wrongful death); *Smith v. Whitaker*, 734 A.2d 243, 249 (N.J. 1999) (survival); *Ryan v. Renny*, 999 A.2d 427, 443 n.1 (N.J. 2010) (loss of consortium); *see also Marie v. McGreevey*, 314 F.3d 136, 140 (3d Cir. 2003) (wrongful death); *Gomez v. H&M Int'l Transp., Inc.*, No. 17-231, 2017 WL 1483306, at *4 (D.N.J. Apr. 24, 2017) (Linares, J.) (survival); *Petrocelli v. Daniel Woodhead Co.*, 996 F.2d 27, 30 (3d Cir. 1993) (loss of consortium). Thus, the Court should deny Defendants' motion to dismiss the PPIMC's wrongful death, survival, and loss of consortium claims for the same reasons that it should deny Defendants requests to dismiss the PPIMC's other causes of action.

E. Amendments Plaintiffs Will Withdraw or Correct

Plaintiffs' revised proposed amended complaints attached hereto all include the following

modifications to alleviate concerns raised in the Defendants' Opposition to Plaintiffs' Motion for Leave to Amend.

1. Wisconsin Implied Warranty

Plaintiffs have withdrawn the implied warranty claims under Wisconsin law.

2. Certain Negligence Per Se Claims

Plaintiffs agree with Defendants that the Court previously dismissed negligence per se claims, as stand-alone claims, under the laws of Arkansas, Arizona, California, Massachusetts, Main, Nebraska, Rhode Island, and Texas. Plaintiffs have addressed this in their proposed amendment by excising out these state-specific claims in the attached revised proposed amended complaints.

3. Certain Strict Liability Claims

Wholesaler Defendants assert that the PPIMC properly excised strict liability failure to warn claims, but the same were not excised from the PMMMC. Plaintiffs have corrected this in the proposed attached amendment. *See* Exs. C-1, C-2.

Plaintiffs also hereby withdraw the strict liability failure to warn and design defect claims arising under the laws of Mississippi, Missouri, South Carolina, and Texas and have done so in the attached a revised Proposed Amended Master Personal Injury Complaint with this filing. *See* Ex. A-1, A-2.

4. Certain Products Liability Act Claims Against Retail Pharmacy Defendants

Plaintiffs hereby withdraw the claims asserted under the Connecticut Product Liability Act and Louisiana Product Liability Act as to the Retail Pharmacy Defendants. *See* Ex. A-1, A-2

5. Parties

Plaintiffs have stricken reference to Major Pharmaceuticals because that entity has availed

itself of the "peripheral defendant" dismissal-without-prejudice process. Plaintiffs have also added two new Arkansas plaintiffs, one to the PELMC and one to the PMMMC.

III. CONCLUSION

For the above-stated reasons, the Court should grant Plaintiffs' Motion for Leave to Amend and instruct the Clerk of the Court to file the attached proposed amended complaints.[39]

Dated: July 12, 2021

Respectfully submitted,

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[39] Plaintiffs reserve the right to seek leave to amend any underlying complaint for the purposes of a potential remand at the appropriate time, if and when necessary.

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of July, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ David J. Stanoch
David J. Stanoch